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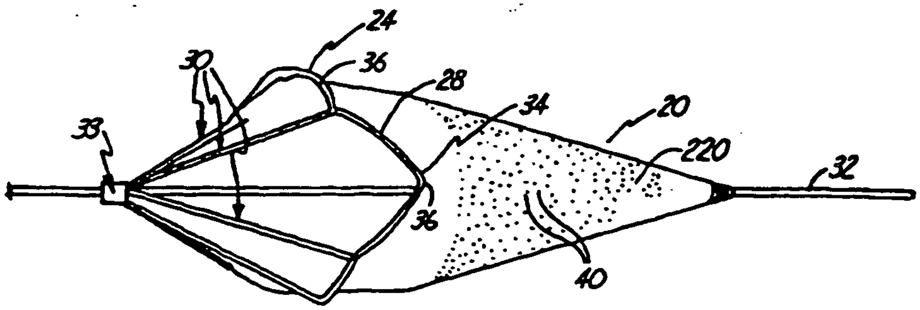

(57) Abstract

A device (20) adapted for deployment in a body vessel for collecting floating debris and emboli in a filter. The device (20) includes a collapsible proximally tapered frame (24) for operably supporting the filter (22) between a collapsed insertion profile and an expanded deployment profile. The tapered collapsible frame (24) includes a mouth (28) which is sized to extend to walls of the body vessel in the expanded deployed profile to seal the filter (22) relative to the body vessel for collecting debris floating in the body vessel.

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DISTAL PROTECTION DEVICE AND METHOD

BACKGROUND OF THE INVENTION

The present invention deals with an emboli capturing system. More specifically, the present invention deals with an emboli capturing system and method for capturing embolic material in a blood vessel during an atherectomy or thrombectomy procedure.

Blood vessels can become occluded (blocked) or stenotic (narrowed) in a number of ways. For instance, a stenosis may be formed by an atheroma, which is typically a harder, calcified substance which forms on the lumen walls of the blood vessel. A stenosis may also be formed of a thrombus material, which is typically much softer than an atheroma but can nonetheless cause restricted blood flow in the lumen of the blood vessel. Thrombus formation can be particularly problematic in a saphenous vein graft ("SVG").

Two different procedures have been developed to treat a stenotic lesion (stenosis) in vasculature. One is deformation of the stenosis to reduce the restriction within the lumen of the blood vessel. This type of deformation, or dilatation, is typically performed using balloon angioplasty.

Another method of treating stenotic vasculature is to attempt to completely remove the entire stenosis, or enough of the stenosis to relieve the restriction in the blood vessel. Removal of the stenotic lesion has been performed through use of radio frequency ("RF") signals transmitted via conductors, and also through use of lasers. Both of these treatments are intended to ablate (i.e., super heat and vaporize) the stenosis. Removal of the stenosis has also been accomplished using thrombectomy or atherectomy. During thrombectomy and atherectomy, the stenosis is mechanically cut or abraded away from the vessel. However, problems may be encountered during thrombectomy and atherectomy because the stenotic debris which is separated from the stenosis is free to flow within the lumen of the vessel. If the debris flows distally, it can occlude distal vasculature and cause significant problems. If it flows proximally, it can enter the circulatory system and form a clot in the neural vasculature or in the lungs, both of which are highly undesirable.

Prior attempts to deal with the debris or fragments produced during thrombectomy and atherectomy have included cutting the debris into pieces small enough (having a size on the order of a blood cell) that they will not occlude vessels within the vasculature. However, this technique has certain problems. For instance, it is difficult to control the size of the fragments which are severed from the stenotic lesion. Larger fragments may be severed accidentally. Also, since thrombus is much softer than an atheroma, it tends to break up easier when mechanically engaged by a cutting instrument. Therefore, at the moment that the thrombus is mechanically engaged, there is a danger that it can be dislodged in large fragments which would occlude the vasculature.

Another attempt to deal with debris severed from a stenosis is to remove the debris as it is severed, using suction. However, it may be necessary to pull quite a high vacuum in order to remove all of the pieces severed from the stenosis. If the vacuum used is not high enough, all of the severed pieces will not be removed. Further, use of a high vacuum may tend to cause the vasculature to collapse.

A final technique for dealing with the fragments severed during atherectomy of the stenosis is placement of a device distal to the stenosis during atherectomy to catch the pieces of the stenosis as they are severed, and removal of those pieces along with the capturing device when the atherectomy procedure is complete. Such capture devices have included expandable filters which are placed distal of the stenosis to capture stenosis fragments. Problems are also associated with this technique. For example, delivery of such devices in a low-profile pre-deployment configuration can be difficult. Further, some devices include complex and cumbersome actuation mechanisms. Also, retrieving such capture devices, after they have captured emboli may be difficult.

SUMMARY OF THE INVENTION

The present invention provides a device adapted for deployment in a body vessel for collecting emboli. The device includes a proximally-tapered collapsible frame for operably supporting the filter between a collapsed insertion profile and an expanded deployment profile. The tapered frame includes a mouth which is sized to extend to walls of a body cavity in the expanded deployed profile for collecting emboli floating in the body cavity.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of an embodiment of a protection device in a radially-expanded deployed profile.

FIG. 2 is a view of the protection device of FIG. 1 in a somewhat collapsed profile.

FIG. 3 is an end view of the protection device of FIG. 1 in a radially-expanded deployed profile.

FIG. 4 is a plan view of a wire mesh sheet for construction of a frame of the protection device illustrated in FIG. 1.

FIG. 5 is a view of the protection device of FIGS. 1-3 in a collapsed profile being inserted through a vessel via an insertion sheath.

FIG. 6. is a view of the protection device of FIGS. 1-3 inserted into a vessel via the insertion sheath, where the insertion sheath is withdrawn to deploy the protection device for operation.

FIG. 7 is a view of the protection device of FIGS. 1-3 operating in a vessel in an expanded deployed profile and illustrating a retrieval sheath for withdrawal of the deployed protection device.

FIG. 8 is a perspective view of an alternate embodiment of a protection device shown in a radially-expanded deployed profile.

FIG. 9 is a view of the protection device of FIG. 8 in a collapsed profile, inserted into a vessel via an insertion sheath.

FIG. 10 is a view of the protection device of FIG. 8 in an expanded deployed profile in a vessel, shown with the insertion sheath withdrawn.

FIG. 11 is a view of the protection device of FIG. 8 in a somewhat collapsed profile being withdrawn from the vessel via a retrieval sheath.

FIG. 12 is a detailed view of portion 120 of the device shown in FIG. 11.

FIG. 13 is a view of an alternate embodiment of a protection device in a collapsed profile being inserted into a vessel via an insertion sheath.

FIG. 14 is a view of the protection device of FIG. 13 in an expanded deployed profile in a vessel.

FIG. 15 is a view of the protection device of FIG. 13 in a collapsed profile being withdrawn from the vessel via a retrieval sheath.

FIG. 16 is a detailed view of portion 16 of the device shown in FIG. 15.

FIG. 17 is a view of a guidewire adapted to support an alternate embodiment of a protection device.

FIG. 18 is a view of an alternate embodiment of a protection device in a collapsed profile, inserted into a vessel via an insertion sheath.

FIG. 19 is a view of the protection device of FIG. 18 in an expanded deployed profile in a vessel, shown with the insertion sheath withdrawn proximally.

FIG. 20 is a view of the protection device of FIG. 18 in a collapsed profile being withdrawn from the vessel via a retrieval sheath.

FIG. 21 illustrates an embodiment of a retrieval sheath for withdrawal of a protection device.

FIG. 22 is a perspective view of an alternate embodiment of a protection device, coupled to a guidewire in an expanded deployed profile.

FIG. 23 is a view of the protection device of FIG. 22 in a collapsed profile in a vessel.

FIG. 24 is a view of the protection device of FIG. 22 in an expanded deployed profile in a vessel.

These drawings are for illustrative purposes only and are not necessarily drawn to scale.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention relates to protection devices deployed in a body vessel or cavity for collection of loosened or floating debris such as embolic material dislodged during atherectomy or thrombectomy.

FIGS. 1-7 illustrate an embodiment of a protection device 20 or filter for collecting loosened debris in a body lumen. As illustrated comparatively in FIGS. 1-2, device 20 operates between a closed collapsed profile, adapted for insertion into a body lumen as illustrated in FIG. 2, and an open radially-expanded deployed profile for collecting debris in a body lumen as illustrated in FIG. 1.

Device 20 includes a filter 22 and a collapsible proximally-tapered frame 24. Frame 24 supports filter 22 and is operably coupled to an elongated guidewire 32 or other support device. Frame 24 includes a mouth 28 and a plurality of longitudinally-extending ribs 30. In an expanded profile, mouth 28 is opened and the ribs extend radially outwardly to support mouth 28. Preferably, a collar 33 movably couples the proximal ends of ribs 30 to guidewire 32. Mouth 28 is thus coupled to collar 33 through ribs 30 and is movable between a collapsed profile and an opened deployed profile, as will be explained.

Preferably, filter 22 is generally cone-shaped, having a proximal and a distal end. The distal end is a narrow, "V"-shaped end and is preferably fixedly secured or formed to guidewire 32. The proximal end has a relatively wide opening and is coupled to mouth 28 of frame 24. Preferably, filter 22 is formed of a polymer membrane. In particular, filter 22 is preferably formed of a porous polyurethane material having a plurality of small openings 40. Filter 22 may be constructed of a polyurethane sheet, and openings 40 may be formed in the polyurethane sheet by known laser techniques. Holes or openings 40 are sized to allow blood flow therethrough but restrict flow of debris or emboli floating in the body lumen or cavity. In the embodiment shown, guidewire 32 extends through mouth 28 of device 20 and along the entire length of the device and is fixed to the distal end of filter 22.

Mouth 28 is generally formed of a pleated ring 34 having an expanded dimension to support filter 22 in the opened deployed profile as illustrated in FIGS. 1-3, and a collapsed dimension to support the filter in the closed collapsed profile as illustrated in FIG. 2. FIG. 3 is an end view of device 20 which illustrates pleated ring 34 in an open expanded profile. In the opened expanded profile, ring 34 includes a plurality of folds 36 which are spaced so that the diameter of the pleated ring 34 forms a mouth of sufficient diameter so that an opening to filter 22 conforms to a desired body lumen. Pleated ring 34 is collapsed by closing folds 36 as illustrated by arrows 38 so that adjacent folds 36 are positioned in close proximity. In such a position, the mouth assumes a relatively small dimension to collapse filter 22 for insertion and retrieval. As previously explained, pleated ring 34 is coupled to guidewire 32 via ribs 30 as shown in FIG. 3.

FIG. 4 illustrates a process of forming frame 24 and folds 36. Frame 24 may be formed from a wire mesh sheet 42 having a series of rows of generally diamond-shaped structures 44. In one preferred embodiment, a portion 46 of a row is cut from wire mesh sheet 42 to form the frame 24. Portion 46 is rolled and sides 50, 52 are joined to form a continuous circular frame. A series of tips 54 on a first end are joined and coupled to ring 33 which slides over guidewire 26. A series of tips 56 on the second end form pleated ring

34 of mouth 28. In particular, tips 56 form the apex of folds 36, which expand and collapse as illustrated by arrows 38 in FIG. 3, to open and close mouth 28. Preferably, the wire mesh sheet 42 is formed of Nitinol or similar material having sufficient elasticity or resilience, as will be explained. The proximal end of filter 22 is then secured to mouth 28 via an adhesive or other suitable connection method. The distal end of filter 22 is then secured to guidewire 26 via adhesive or other techniques.

FIGS. 5-7 illustrate operation of protection device 20 which is inserted into a body lumen to collect floating debris or emboli. Briefly, as shown in FIG. 5, device 20 is inserted into a body lumen 60, such as a vascular lumen having a stenosis 62. Device 20 may be deployed distal of the blocked region or stenosis 62 to capture calcified material or substances dislodged during a medical procedure to open the stenosis 62. The stenosis 62 in a coronary vessel may be opened by known medical procedures such as dilatation or atherectomy.

More specifically, as shown in FIG. 5, device 20 is first collapsed and inserted in the collapsed profile into a delivery sheath 64. Sheath 64 is formed of a tubular member 66 including an inner lumen 68 extending therethrough. The profile of sheath 64 is relatively small to facilitate insertion and placement of device 20. Device 20 is placed in lumen 68 for insertion. Folds 36 of frame 24 are collapsed and are maintained in the collapsed profile by the inner surface of lumen 68. In the collapsed profile, collar 33 slides proximally along guidewire 32 to accommodate for the proximal longitudinal movement of ribs 30 as device 20 is collapsed. Once device 20 is inside delivery sheath 64, sheath 64 is inserted through the vasculature of a patient and has its distal end positioned distal of the stenosis or blocked region 62.

To deploy device 20 after it is suitably located, sheath 64 is withdrawn as illustrated by arrow 70 in FIG. 6, thus releasing the pressure exerted via the tube 66 to maintain frame 24 in the collapsed profile. Thus, folds 36 resiliently separate to open mouth 28 and the filter 22 for operation, as illustrated in FIG. 6. Mouth 28 is sized so that when folds 36 separate, mouth 28 conforms to the dimensions of vascular lumen 60. Mouth 28 supports filter 22 relative to the circumference of vascular lumen 60 so that blood flows through the filter and debris and particles floating in the blood are trapped by the filter. In particular, holes 40 of the filter allow blood to flow therethrough, but restrict flow of debris and clotting material so that loosened debris does not migrate and clog alternate body sites.

Preferably, as previously explained, frame 28 is formed of a Nitinol alloy or other elastic material so that the frame "springs" back to an expanded profile after the confining force imparted via sheath 64 is released. The relatively elastic material provides sufficient resilient force for a tight interaction between mouth 28 and lumen 60 to assure that blood flows through filter 22 to capture floating debris and particles.

After deployment, sheath 64 may be completely withdrawn and various treatment devices, such as an angioplasty dilatation catheter, stent delivery catheter or other atherectomy or thrombectomy devices, may be inserted for treatment. The treatment devices are inserted over guidewire 32 for placement relative to the treatment site. After treatment is complete, device 20 is removed as illustrated in FIG. 7.

As shown in FIG. 7, a retrieval sheath 72 is inserted as illustrated via arrow 74 for removal of device 20. Retrieval sheath 72 is formed of a tubular member 75 having a central lumen 76 and a distal opening sized to capture device 20. Retrieval sheath 72 is inserted to align the distal opening of sheath 72 with the proximal end of frame 24. Thereafter, sheath 72 is advanced; or, alternatively, in the embodiment shown, guidewire 32 is retracted, to collapse ribs 30, thereby collapsing mouth 28 and filter 22 as illustrated by arrows 78. In particular, ribs 30 (and the frame 24) are proximally sloped or tapered so that as sheath 72 is advanced over ribs 30, they collapse radially inwardly and collar 33 rides proximally on guidewire 32. As ribs 30 collapse inwardly, frame 24 folds at folds 36 until mouth 28 resides within retrieval sheath 72, or closely proximate the distal end of sheath 72, thereby trapping emboli therein. Device 20 and sheath 72 are then withdrawn from the vasculature.

Although longitudinally sloped ribs 30 are coupled to collar 33 in the device shown, ribs 30 may be directly fixed to guidewire 32 so that the filter is loosely supported in the collapsed profile. Alternatively, the device may be supported via an alternate core wire or guidewire structure (not shown) which is coupled to frame 24 via ribs 30 but unlike guidewire 32 does not extend through the mouth and along the entire length of the filter so that device 20 does not have radial slack in the collapsed profile. Also, although device 20 is shown inserted distal of stenotic region 62 to capture material and debris dislodged during a treatment procedure, device 20 may be deployed in alternate positions for capturing floating debris or particles in other body cavities.

FIGS. 8-11 illustrate an alternate embodiment of a protection device 90. As illustrated in FIG. 8, protection device 90 includes a filter 92, a frame 94 and a collar 96. Protection device 90 is operably coupled to a guidewire 32 for operation as will be explained. Guidewire 32 is a typical guidewire having a small diameter for insertion into a tract to a treatment site, and preferably includes a spring coil tip.

Filter 92 includes a cone-shaped porous portion 100 and a pleated portion 102. Porous portion 100 includes a plurality of openings 104 to permit blood flow through filter 92 while restricting flow of debris or particles. A distal tip 106 of filter 92 is fixedly secured to guidewire 32. Preferably, filter portion 100 is formed of a polymer material, such as a polyurethane material, and holes or openings 104 are formed via known laser techniques.

Collar 96 is preferably formed of a relatively short tubular member having an inner lumen 108 and having notches 110 formed on an outer perimeter. Guidewire 32 extends through lumen 108 so collar 96 is slidably coupled to guidewire 32. Frame 94 is coupled to collar 96, and filter 92 is coupled to frame 94.

Preferably, frame 94 is formed of an elongated wire 112 having opposed ends. Opposed ends of wire 112 are coupled to collar 96 to form a mouth, and filter 92 (in particular, pleated portion 102) is coupled to wire 112 along substantially the entire length of wire 112. Preferably, guidewire 32 extends through collar 96 and through the mouth and extends along the entire longitudinal length of filter 92. Thus, collar 96 is moved proximally as illustrated by arrow 114 to collapse the mouth formed by frame 94 for insertion. Collar 96 is slid distally to expand the mouth formed by frame 94 and filter 92 to a deployment position.

Preferably, wire 112 is formed of a relatively elastic material such as Nitinol. Filter portion 102 is secured to wire loop 112 by one of various suitable attachment methods, including adhesives, stitching, or other known methods, to define the mouth of the device 90. Ends of wire 112 are also preferably coupled to collar 96 by known attachment methods, including adhesives.

Preferably, pleated filter portion 102 is formed of a polymer material such as polyurethane. The pleated filter portion 102 is preferably manufactured by winding a wire or other suitable coil around a polymer tube material. After the wire is wound around the tube, the tube is pressurized, causing the tube material to expand between the gaps in the wire, creating the pleats or creases which allow portion 102 to collapse. The coil is then removed, leaving collapsible portion 102. Construction of collapsible portion 102 is described in St. Germain, U.S. Patent No. 5,534,005, issued July 9, 1997, and assigned to Scimed Life Systems, Inc., hereby incorporated by reference.

The pleated filter portion 102 allows for the filter to expand or extend longitudinally to absorb impact pressure caused by embolic material received by filter portion 92 to maintain the placement of the device 90 during operation. Filter portion 100 and pleated portion 102 may be formed separately or from a single sheet of polymer material.

FIGS. 9-12 illustrate operation of device 90 in a patient's vasculature. Some parts are similar to those shown in FIGS. 5-7, and similar numbers are used to identify similar parts. As shown in FIG. 9, device 90 is inserted in a collapsed profile in cooperation with an insertion sheath 64 similar to that shown and described in FIG. 5. Tube 66 exerts a force on wire 112 and filter portions 100, 102 to collapse device 90. As illustrated, in the collapsed profile, collar 96 moves along wire 32 to longitudinally accommodate for radial slack of the collapsed device 90. Sheath 64 and device 90 are advanced to a deployment site, preferably distal of a stenotic region 62, for operation during a treatment procedure.

Once device 90 and sheath 64 are located at the deployment site, sheath 64 is withdrawn (while the position of guidewire 32 is maintained) as illustrated by arrow 116 so that the wire 112 expands radially outwardly (since the compression force is released). This causes filter 92 to expand to conform to the inner diameter of the vessel 60. As wire 112 expands outwardly, collar 96 slides distally along guidewire 32 for radial expansion of wire 112 and filter 92. Preferably, as previously explained, wire 112 is formed of a sufficiently elastic material to essentially spring outwardly after pressure is released, so that a tight interference between frame wire 112 and the vessel walls of vessel 60 is maintained. This helps to ensure that the device 90 is sufficiently lodged against vessel wall 60 so that it stays in position during treatment and is not dislodged as a result of blood flow through the filter 92. In particular, sufficient pressure must be maintained so that the filter conforms to the diameter of vessel 60 and does not migrate due to force imparted to the filter when debris collects in the filter and so that no embolic material can slip between the filter and the walls of vessel 60.

Thereafter, treatment devices (not shown) may be advanced along guidewire 32 for placement relative to a stenosis 62 for treatment. Such treatment devices may include a dilatation catheter, stent delivery catheter or atherectomy or thrombectomy devices, etc. After treatment is completed, device 90 may be withdrawn as illustrated in FIGS. 11 and 12. Device 90 is withdrawn via a retrieval device 120. Retrieval device 120 is formed of a tubular member 122 having an inner lumen 124 and a locking tab 126 formed on an inner surface of the tubular member 122. Locking tab 126 mates with notch 110 formed on collar 96 for retrieval and removal of device 90.

Preferably, locking tab 126 is formed of a rigid extension having a sloped camming surface 130 and a flat locking surface 132. Notch 110 also includes a camming surface 134 and a flat locking surface 136. The camming surfaces 130, 134 are aligned so that, as sheath 120 is advanced, camming surfaces 130, 134 mate to slightly expand tube 122 so that locking member 126 on sheath 120 advances past notch 110 until the locking surfaces 132, 136 align and the camming force is released. This allows tube 122 to collapse to its original dimension with surfaces 132, 136 aligned to lock device 90 to sheath 120 for withdrawing device 90. Sheath 120 is withdrawn proximally, as illustrated by arrow 140, while maintaining the position of guidewire 32. This causes collar 96 to slide proximally to collapse device 90 along guidewire 32 thereby drawing wire 112 down over wire 32 and collapsing device 90. Once device 90 is collapsed, guidewire 32 and sheath 120 are collectively withdrawn to remove collapsed device 90.

FIGS. 13-16 illustrate an alternate embodiment of a protection device 150 where similar numbers are used to identify similar parts of previous embodiments. Device 150 is shown in operation in a vessel 60 having a stenosis 62. Device 150 includes a filter 152, a frame 154, and a collar 156. Device 150 is operably coupled to guidewire 32 for operation. Filter 152 is preferably a cone-shaped member having proximal and distal ends 158, 160. The distal end 160 is generally "V"-shaped. Filter 152 may be formed from a polymer sheet material similar to that described for previous embodiments and filter holes or openings 180 may be formed therein by laser techniques. Material and debris generally collect at the "V"-shaped tip to limit interference with blood flow through filter 152. The "V"-shaped end 160 is fixedly coupled relative to guidewire 32. Proximal end 158 includes an opening which is supported relative to frame 154 to form a mouth of the device, as will be explained. Collar 156 is a tubular member 164 having an inner lumen 166 slidably coupled relative to guidewire 32.

Frame 154 includes a generally circular mouth member 170 and a plurality of struts or ribs 172. Mouth 170 supports filter 152 and is preferably formed of a wire loop which is coupled thereto via a known adhesive or other suitable means. The mouth is coupled to collar 156 via struts or ribs 172 so that the collar slides along guidewire 32 to selectively longitudinally extend device 150 to collapse device 150 for insertion and retrieval, and longitudinally shorten device 150 to expand device 150 (and mouth 170) for deployment. Preferably, struts 172 are attached to collar 156 and mouth 170 by any suitable means. Preferably, frame 154 (mouth 170 and struts or ribs 172) are formed of a wire or strip of a relatively elastic material such as a Nitinol material.

Device 150 includes compression spring 176 to bias device 150 in the longitudinally shortened (and thus radially expanded) profile having mouth 170 radially expanded for operation. In particular, spring 176 includes opposed ends, a first end is attached to collar 156, and a second end is attached to end 160 of filter 152. The compression spring 176 is normally biased to compress as illustrated by arrows 178 to bias the device in an opened deployed profile.

For insertion, device 150 is maintained in a low-profile position via sheath 64 as illustrated in FIG. 13 similar to that described for previous embodiments. In particular, sheath 64 exerts a force on frame 154 and filter 152 to compress frame 154 and filter 152 against the spring bias provided by compression spring 176. As shown in FIG. 13, insertion sheath 64 and device 150 are inserted into a patient and located distal of a stenosis 62 for deployment.

To deploy the device, the sheath 64 is withdrawn while the operator maintains the position of guidewire 32. Once sheath 64 is withdrawn from device 150, frame 154 and filter 152 expands radially outwardly under the force of the compression spring 176 to expand mouth 170 to conform to the vessel walls 60 as illustrated in FIG. 14. Ribs 172 are extended outwardly to support mouth 170 in a radially-expanded position. The spring 176 maintains device 150 in a deployed position so that mouth 170 conforms to the opening of the vessel. Debris is captured and device 150 does not migrate under the load of the debris collected in filter 152.

After treatment is completed, device 150 may be withdrawn. Preferably, device 150 is withdrawn via a removal sheath 184 , as illustrated in FIGS. 15-16. The removal sheath 184 includes an outer tubular extent 186 supporting an inner tube 188. The inner tube 188 includes a docking tip 190. Docking tip 190 includes docking latch 192 which cooperate with a latch 194 formed on an inner surface of collar 156. Docking latch 192 is formed of an arrow tip 190 defining sloped camming surface 196 and a lateral locking surface 198. Latch 194 on collar 156 includes a camming surface 200 and a lateral locking surface 202.

Sheath 184 is advanced over the guidewire 32 to insert tip 190 through the opening in tubular collar 156. Tip 190 is advanced until camming surfaces 196, 200 expand collar 156 to further advance arrow-shaped tip 190 until collar 156 collapses to align locking surfaces 198, 202 to lock device 150 to sheath 184 for withdrawal. After device 150 is locked to sheath 184, retrieval device 184 is first withdrawn proximally, as illustrated by arrow 204, while maintaining the position of guidewire 32 to force the frame 154 and filter 152 against the spring bias to a low-profile dimension. Thereafter, retrieval sheath 184 and guidewire 32 are collectively proximally withdrawn as illustrated to remove the device.

An alternate embodiment of a protective device is illustrated in FIGS. 17-20 and is formed independently of a guidewire 210. Guidewire 210 is formed of an elongated wire 212, preferably having a spring coil tip 214, and a protective device docking member 216 coupled to a distal portion of wire 212, as illustrated in FIG. 17. Docking member 216 is rigidly coupled to wire 212 and in one embodiment is formed of a generally "V"-shaped member 218 including a docking channel 220. Member 218 includes groove 222 which opens to channel 220. Docking member 216 is used to removably secure a protection device thereto as will be explained.

Docking member 216 may be permanently formed on the guidewire 210. Alternatively, docking member 216 may be detachably connected to guidewire 210 such as by a friction fit between guidewire 210 and a channel (not shown) of the docking member 216 or by a mechanical attachment mechanism. If a detachable, docking member 216 may be used on any suitable guidewire, thereby adapting the guidewire for operation with a protection device.

FIG. 18 illustrates an embodiment of a protection device 230 which may be selectively coupled to docking member 216. Protection device 230 includes a distal cone 232, a filter 152, a frame 154, and a collar 156. Cone 232 is coupled to a distal end of filter 152. Cone 232 is generally "V"-shaped and is formed of a rigid member having a distal opening (not shown) sized for insertion of guidewire 210 therethrough. Cone 232 includes a locking ring 242 extending about an outer perimeter of cone 232. Locking ring 242 is sized for insertion into groove 222 of docking member 216.

Thus, device 230 is mounted relative to the guidewire by inserting guidewire 210 through an opening in cone 232. Device 230 is advanced over guidewire 210 to align cone 232 with docking member 216. Cone 232 is forced into channel 220 of docking member 216 until ring 242 snaps into groove 222 and is maintained therein. Device 230 is inserted in a low-profile collapsed condition via cooperation with sheath 64, and is deployed by withdrawing sheath 64 while maintaining the position of guidewire 210 after device 230 is positioned at a treatment site (as comparatively illustrated in FIGS. 18-19) similar to that previously described with reference to FIGS. 13-14.

FIG. 20 illustrates withdrawal of device 230 via retrieval sheath 184, as previously described with reference to FIGS. 15-16. Sheath 184 is coupled to collar 156 and is then withdrawn proximally while maintaining the position of guidewire 210 to collapse device 230 to a low profile. Thereafter, sheath 184 and guidewire 210 are withdrawn to remove guidewire 210, protection device 230, and sheath 184 from the patient after treatment.

FIG. 21 illustrates an embodiment of a retrieval sheath 280 for operation with a distal protection device 282 for collapsing the distal protection device for withdrawal. The retrieval sheath 280 includes a telescoping tubular structure including an outer tubular member 283 and an inner tubular member 284. Outer tubular member 283 includes a lumen 286, and inner tubular member 284 extends through lumen 286 and is movable therein to form the telescoping tubular structure.

Outer tubular member 283 is formed of a composite structure including a first tubular portion 288 and a second tubular portion 290. The first tubular portion 288 includes a proximal end (not shown) and a distal end 292. The second tubular portion 290 includes a proximal end 294 and a distal end 296. Proximal end 294 is coupled to distal end 292 of tubular member 288 to form a composite outer tubular structure 283 having a proximal end (not shown) and distal end 296.

Inner tube 284 includes a proximal end (not shown) and a distal end 298. Inner tube 284 includes a first diameter portion 300, a second diameter portion 304, a transition portion 306, and tapered flanged end 308. First and second portions 300, 304 are coupled via transition portion 306. Flanged end 308 has a relatively large tapered mouth for capturing and progressively collapsing a deployed protection device as will be explained.

The proximal end of inner tube 284 extends through outer tube 283 and exits from proximal end of outer tube 283 for providing a mechanism for slidably moving inner tube 284 within outer tube 283. Flanged end 308 is relatively flexible and resilient and is biased in a radially expanded position so that it opens to an expanded tapered profile, as illustrated in FIG. 21, when flanged end 308 extends beyond distal end 296 of outer tube 283. When flanged end 308 is retracted within inner tube 283 as illustrated via arrow 310, flanged end 308 collapses as illustrated by arrows 312 to assume the dimension of outer tube 283 in a collapsed position (not shown). Flanged end 308 may be formed of a pleated material or simply a relatively elastic material.

In operation, retrieval sheath 280 is inserted into a patient's vasculature with flanged end 308 in a collapsed position within inner tube 283 to provide a low profile for insertion. Retrieval sheath 280 is inserted and aligned closely proximate to deployed protection device 282. Once retrieval device 280 is aligned, inner tube 284 is slid distally relative to outer tube 282 to expand flanged end 308 to an expanded profile, as illustrated in FIG. 21, to surround the deployed protection device. Thereafter, sheath 280 may be advanced, or protection device 282 may be withdrawn proximally via guidewire 32 to forcibly collapse protection device 282 as protection device 282 is withdrawn along the tapered inner channel of flanged end 308. Retrieval device 280, protection device 282, and guidewire 32 are then withdrawn. The device thus provides a system for capturing a protection device 282 and filtered contents (debris, emboli, etc.) along therewith to minimize post-procedural embolic events. Preferably, inner and outer tubes 282, 284 are formed of a polymer material, and flanged end 308 is formed of a polymer membrane. Although a particular embodiment of retrieval device 280 is shown, it should be understood that construction of device 280 is not limited to the exact construction shown.

FIGS. 22-24 illustrate an alternate embodiment of a distal protection device 320. As shown in FIG. 23, distal protection device 320 is coupled to a guidewire 322 to operate between a radially-expanded deployed profile illustrated in FIGS. 22 and 24, and a collapsed profile illustrated in FIG. 23 for insertion and retrieval. Guidewire 322 is formed of a tubular member 324 including a central lumen 326 therethrough. The guidewire 322 may be formed of a hypo tube or other material. The distal protection device 320 includes a filter 328 and a frame 330.

Preferably, frame 330 is formed of an elongate wire 332 and a polymer sleeve 334. Frame 330 is coupled to guidewire 322 and is supported thereby between the insertion dimension illustrated in FIG. 23 and the deployed dimension illustrated in FIGS. 22 and 24. Filter 328 is coupled to frame 330 and is supported thereby at its proximal end by frame 330. Filter 328 may be formed of a polymer sheet material or a mesh-like material having holes or openings 336 therein to allow blood to flow therethrough while restricting flow of emboli, debris and clotting material. Filter 328 is cone-shaped, preferably having a "V"-shaped tip and a large opening to funnel debris for collection. Filter 328 and sleeve 334 may be integrally or separately formed, and secured via known attachment methods such as known adhesives.

Guidewire 322 includes spaced distal openings 338, 340 which communicates with inner lumen 326. Opposed ends of sleeve 334 are coupled to spaced openings 338, 340 so the lumen through sleeve 334 forms a path for frame wire 332. Frame wire 332 extends from a proximal end (not shown) of the guidewire 322 through lumen 326, through openings 338 and 340, and is anchored at a distal end of lumen 326 (preferably proximate to opening 340). Frame wire 332 also extends through sleeve 334 to form an external loop 342 defining the mouth of the protection device 320. External loop 342 is tightened by pulling the wire 332 proximally, and is opened by pushing the wire 332 distally, as illustrated by arrow 344, to open and close the mouth of protection device 320.

FIGS. 23-24 illustrate operation of protection device 320. As illustrated in FIG. 23, the device is inserted in a low-profile dimension by proximally retracting wire 332 to close external loop 342 to locate device 320 at a deployment site, preferably distal of a stenosis 62. Frame wire 332 is moved distally as illustrated by arrow 344 to expand loop 342 to open the mouth to filter 328 to conform to the dimension of vascular lumen 60, as illustrated in FIG. 24. As the mouth of the device 320 is expanded to conform to the vascular dimension, guidewire 322 pushes against a lumen wall to provide a tight fit between filter 328 and vascular wall 60.

The mouth has a dimension which conforms to the vascular wall, and cone-shaped filter 328 funnels material to a tip of the filter to allow bloodflow to continue therethrough. Device 320 is collapsed after use for removal. To collapse the device for withdrawal, frame wire 332 is moved proximally, as illustrated by arrow 346 in FIG. 24, to collapse or close external loop 342 to the low-profile collapsed dimension illustrated in FIG. 23.

In the embodiment illustrated in FIGS. 23-24, a pressure-sensing device 350 may be inserted through lumen 326 of guidewire 322. The pressure-sensing device 350 is formed of an elongated member 352 having a distal tip 354 which is curve-shaped to align a pressure sensor facing the direction of blood flow or fluid flow through vessel 60. Proximal circuitry is coupled to the pressure sensor at distal tip 354 to provide a pressure reading to an operator. Of course, device 350 may simply be a hollow tube with the pressure sensing mechanism located entirely at a proximal end of device 350. The pressure reading indicates whether the blood vessel or vascular vessel 60 is occluded distal of protection device 320, to ensure proper blood flow through protection device 320. Thus, if emboli, particles, or debris clogs filter 328 of distal protection device 320, the pressure will drop, thus indicating restricted blood flow for real-time monitoring of blood flow through the distal protection device 320. Use of a pressure sensor provides advantages over use of dye-injection techniques to provide continuous real-time quantitative measurement of blood flow for monitoring operation.

Although the protection devices described are illustrated for use as temporary filters, it should be understood that the devices of the present invention are not so limited and may be used for permanent filters which are retained in a patient to filter debris and clotting material. Although the present invention has been described with reference to preferred embodiments, workers skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

WHAT IS CLAIMED IS:

1. A device adapted for deployment in a body vessel, comprising:

   a filter having a plurality of openings for fluid flow therethrough; and

   a proximally-tapered collapsible frame coupled to the filter and operably coupled to a guidewire, said frame including an expandable mouth coupled to the filter and adapted to operate between an expanded profile and a collapsed profile, and longitudinal ribs having opposed first and second ends, said first ends being coupled to the guidewire, and said second ends being coupled to the mouth, said ribs being sloped outwardly in an expanded position to form the proximally tapered collapsible frame.

2. The device of claim 1 wherein the mouth is normally biased in the expanded profile.

3. The device of claim 2 wherein the mouth is formed of a resilient wire material.

4. The device of claim 1 wherein the mouth and ribs are integrally formed from a mesh sheet material.

5. The device of claim 1 wherein the filter has a distal end fixedly coupled to the guidewire.

6. The device of claim 1 wherein the filter is generally cone-shaped.

7. The device of claim 1 wherein mouth is formed of a pleated ring.

8. The device of claim 1 wherein ribs are fixedly secured to the guidewire.

9. The device of claim 1 and further comprising a collar slidably disposed over the guidewire and wherein the ribs are coupled to the collar, the guidewire extending through the mouth and along a length of the filter.

10. The device of claim 1 wherein the frame includes at least four ribs.

11. The device of claim 7 wherein the pleated ring includes at least four folds.

12. The device of claim 1 wherein the mouth and ribs are integrally formed.

13. In combination:

a device adapted for deployment in a body vessel including:

a filter having a plurality of openings for fluid flow therethrough, said filter being adapted to be coupled to a wire for operation;

a proximally-tapered collapsible frame coupled to the filter and operably coupled to the core wire, said frame including an expandable mouth adapted to operate between an expanded profile and a collapsed profile, and sloped longitudinal ribs having opposed first and second ends, said first ends being coupled to the wire and said second ends being coupled to the mouth, said ribs being sloped outwardly in the expanded profile to form the proximally-tapered collapsible frame; and a sheath formed of a tubular member sized for placement over the ribs to collapse the mouth and filter to the collapsed profile.

14. A method for deploying a device in a vessel for collecting debris, comprising the steps of:

providing a device coupled to a guidewire and movable relative thereto, having a filter and a frame for supporting the filter in a collapsed profile and an expanded deployed profile, said frame being normally biased in the expanded deployed profile;

providing an elongated sheath having proximal and distal ends and an inner lumen extending therethrough;

positioning the device in the lumen of the sheath to maintain the device in a collapsed profile;

inserting the sheath and device into a body lumen and advancing the distal end of the sheath to locate the device at a deployment site; and

proximally moving the sheath to withdraw the sheath while maintaining the position of the guidewire to remove the sheath from the device to expand the frame and filter.

15. The method of claim 14 wherein the guidewire is concurrently inserted with the device and sheath.

16. The method of claim 14 wherein the guidewire is inserted prior to insertion of the device, and the device is advanced over the guidewire for placement at

the deployment site and is locked to the guidewire prior to withdrawal of the sheath.

17. The method of claim 14 wherein a pressure sensor device is inserted distal of the deployed device for monitoring blood flow.

18. A method for removing a deployed device, deployed in an expanded operating profile for collecting debris from a vessel, comprising the steps of:

providing the device with a proximally tapered collapsible frame for supporting a filter, said proximally tapered frame including a plurality longitudinally sloped ribs extending radially outwardly in a deployed profile;

providing an elongated sheath having proximal and distal ends and an inner lumen extending therethrough;

inserting the elongated sheath to align the distal end thereof with the longitudinally sloped ribs of the deployed device;

positioning the sheath over the longitudinally sloped ribs to collapse the device; and

proximally withdrawing the sheath and device.

19. The method of claim 18 wherein the device is fixedly coupled to a guidewire, and wherein positioning the sheath comprises:

proximally withdrawing the guidewire to collapse the device within the sheath.

20. The method of claim 18 wherein positioning the sheath comprises:

advancing the sheath over the sloped ribs to collapse the device.

21. The method of claim 18 and further comprising: positioning at least a proximal mouth of the device within the sheath prior to withdrawing the sheath and device.

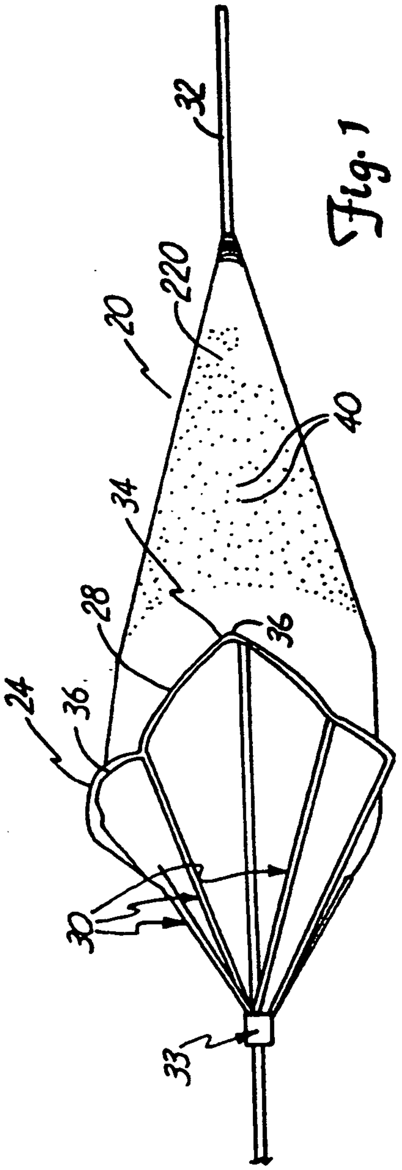

Fig. 1

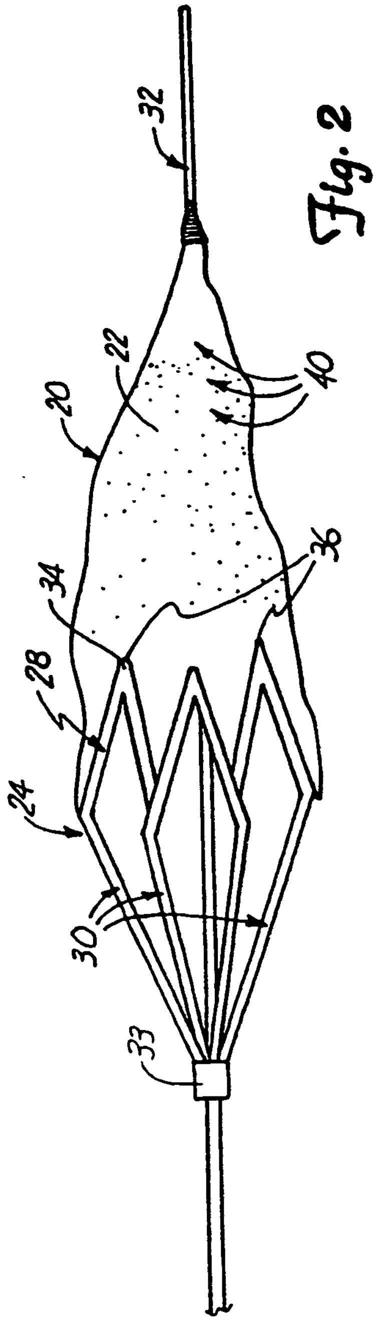

Fig. 2

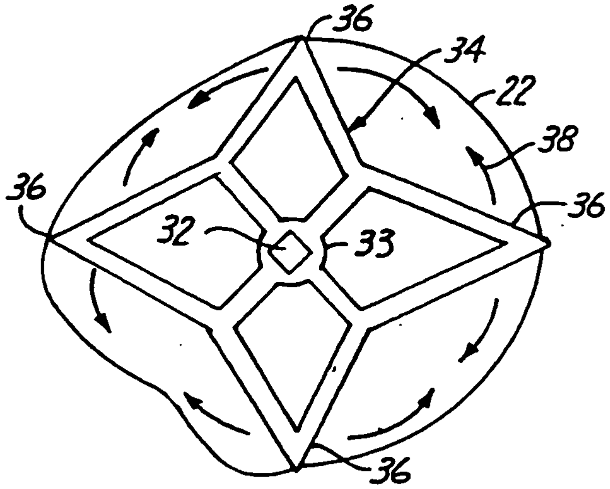

Fig. 3

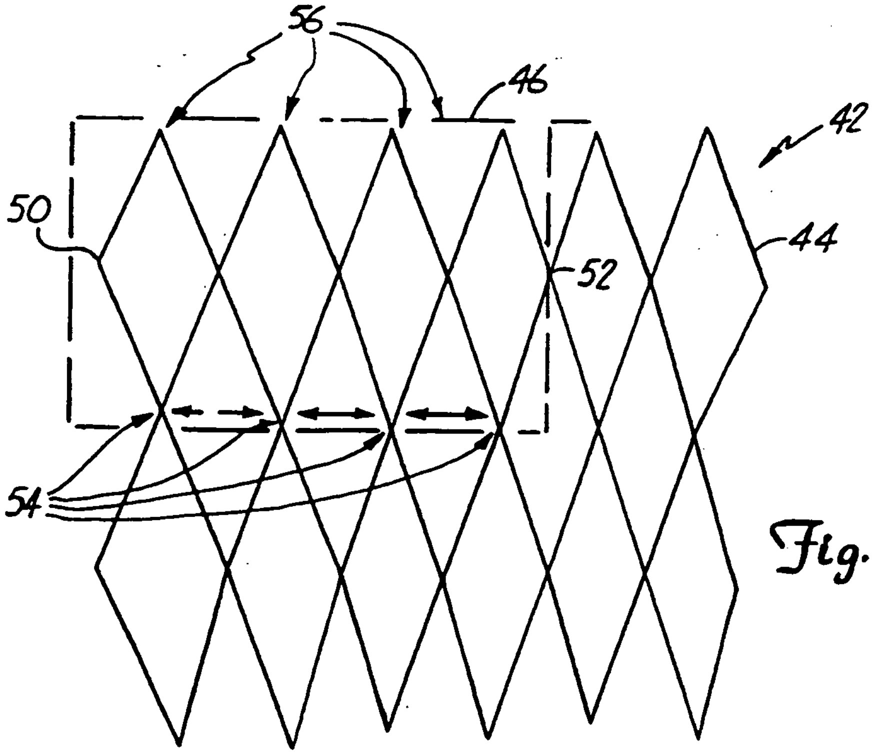

Fig. 4

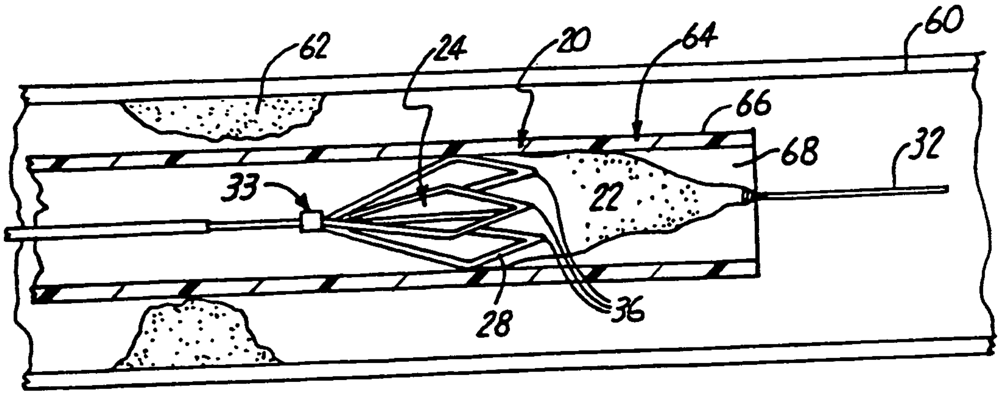

Fig. 5

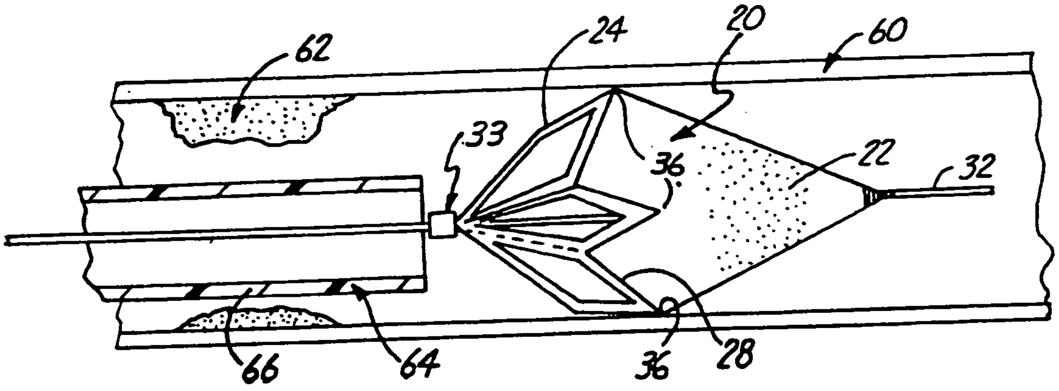

Fig. 6

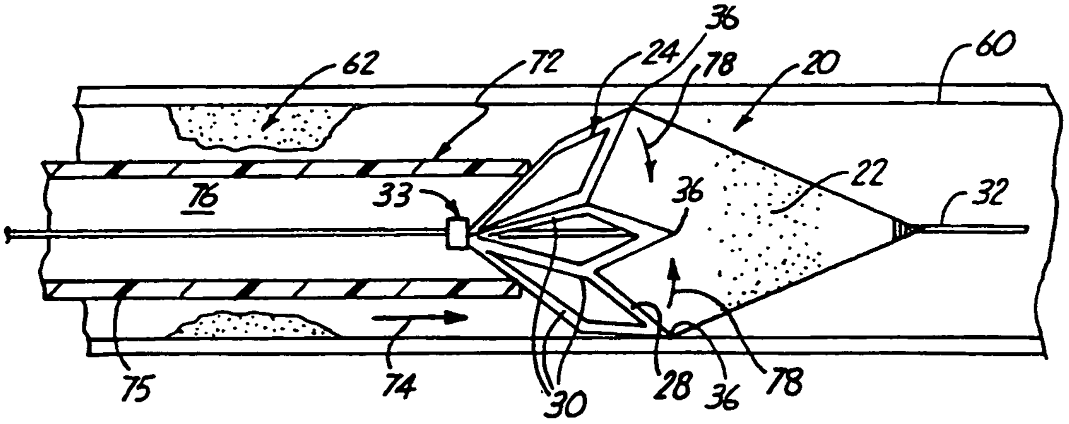

Fig. 7

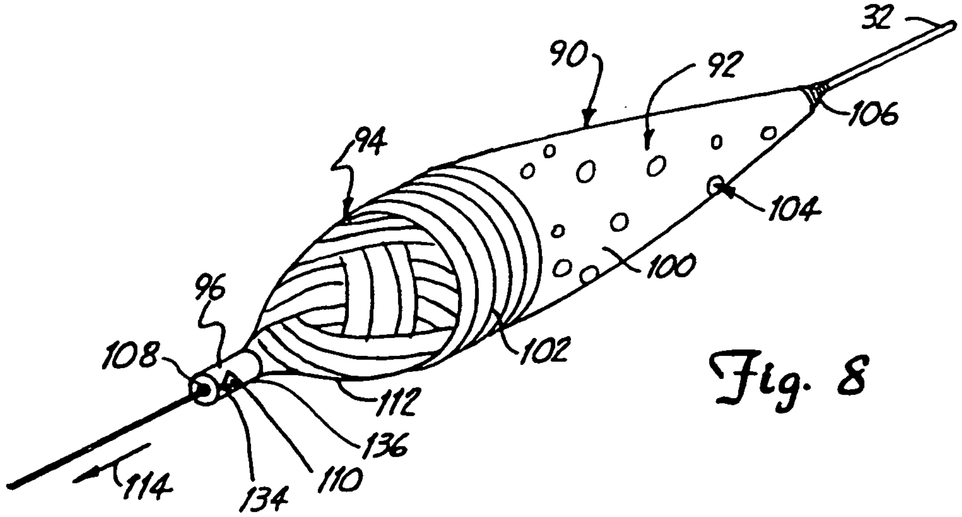

Fig. 8

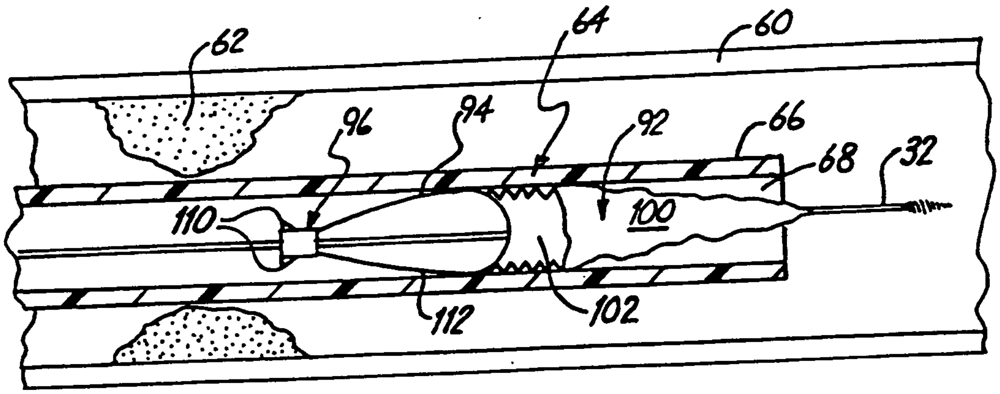

Fig. 9

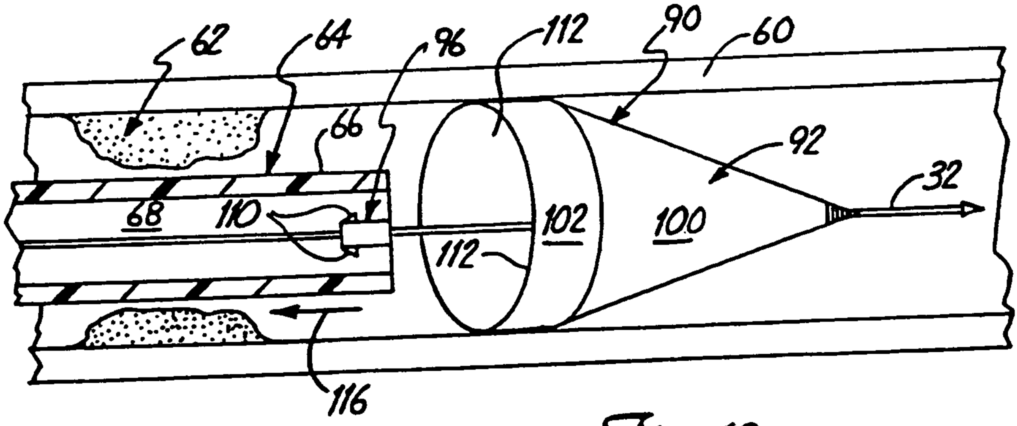

Fig. 10

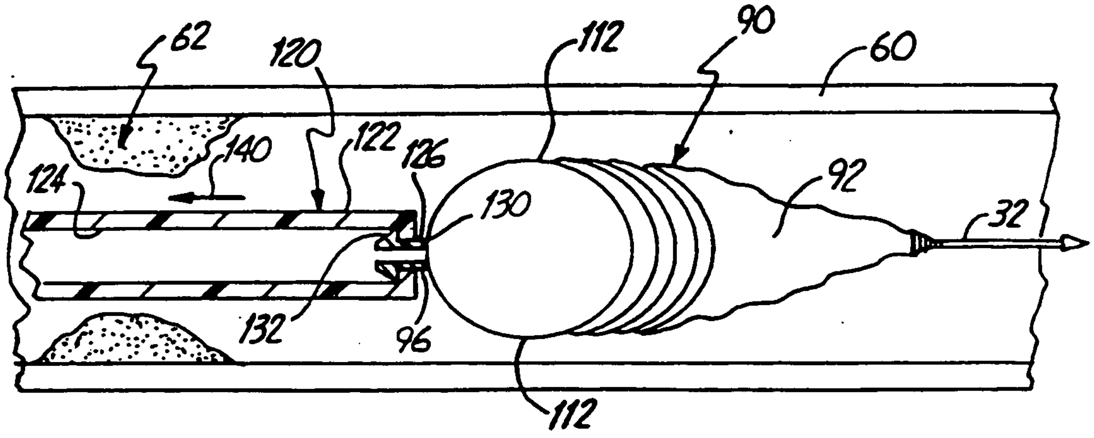

Fig. 11

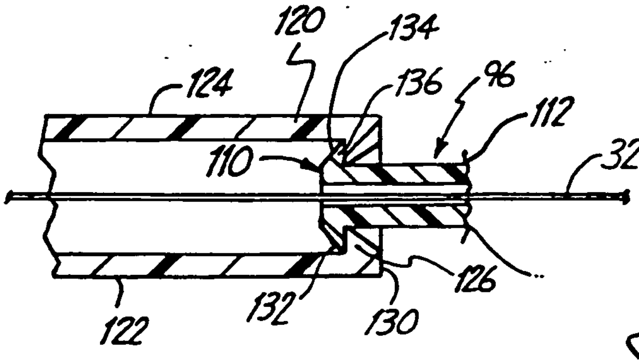

Fig. 12

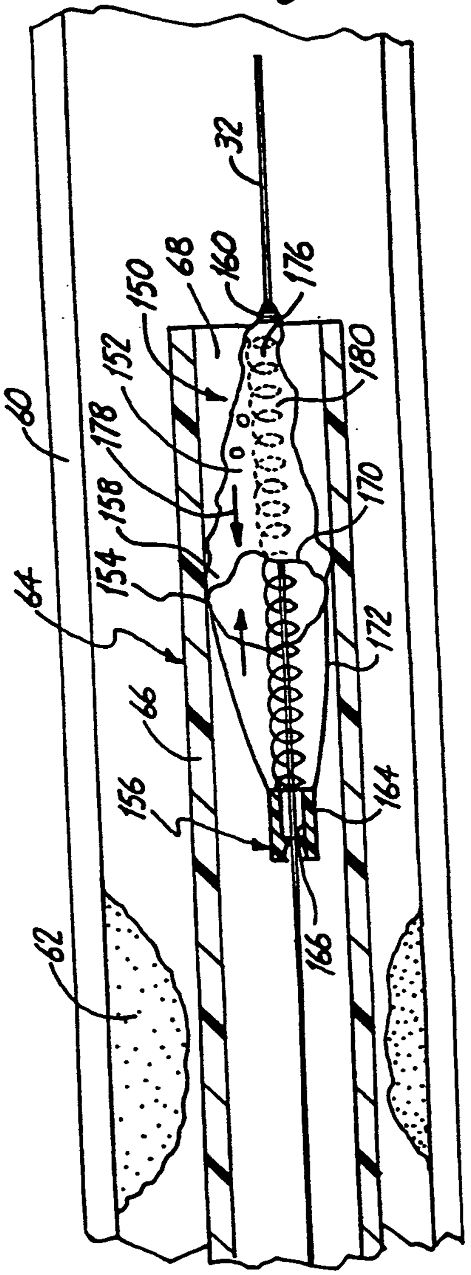

Fig. 13

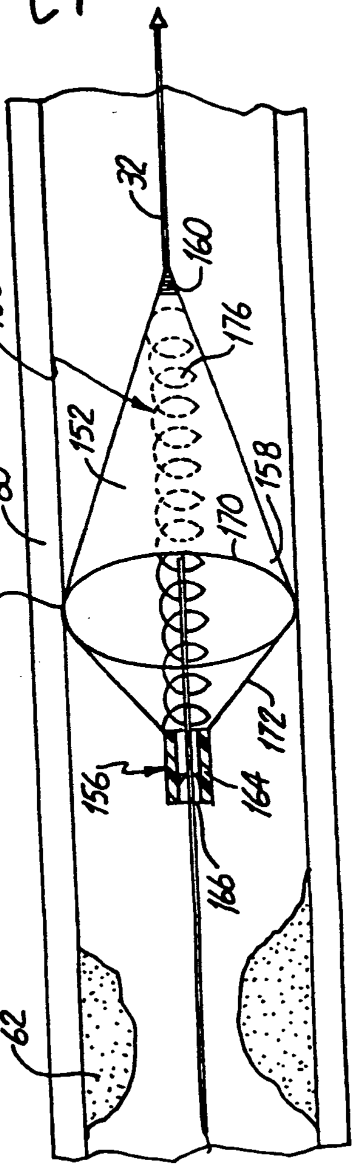

Fig. 14

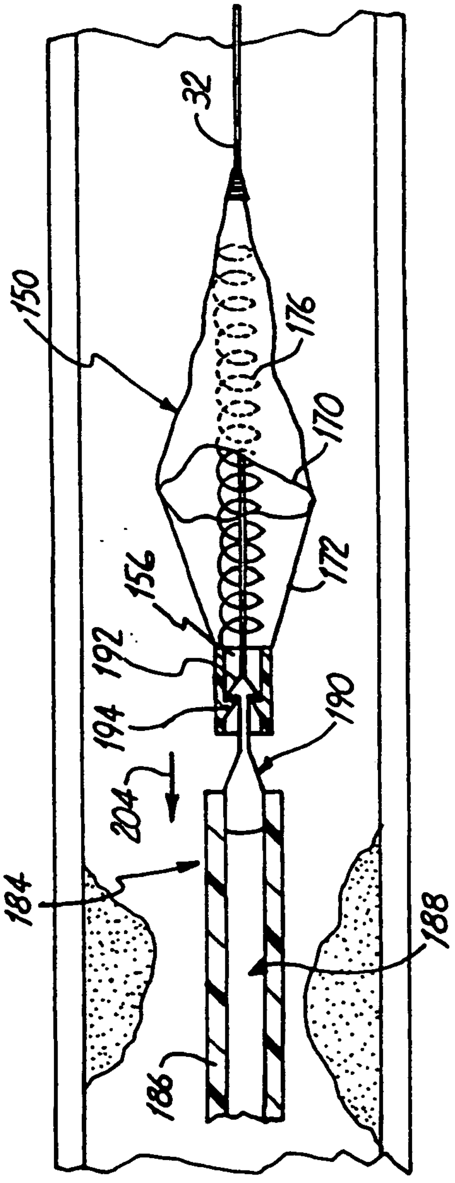

Fig. 15

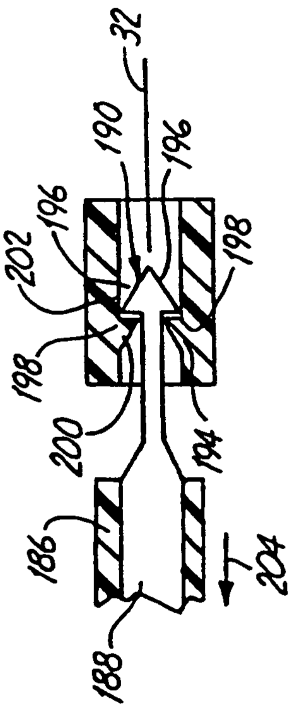

Fig. 16

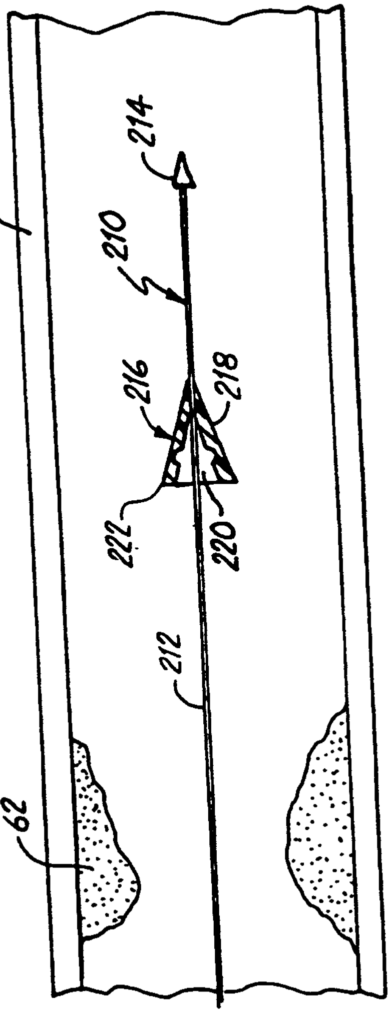

Fig. 17

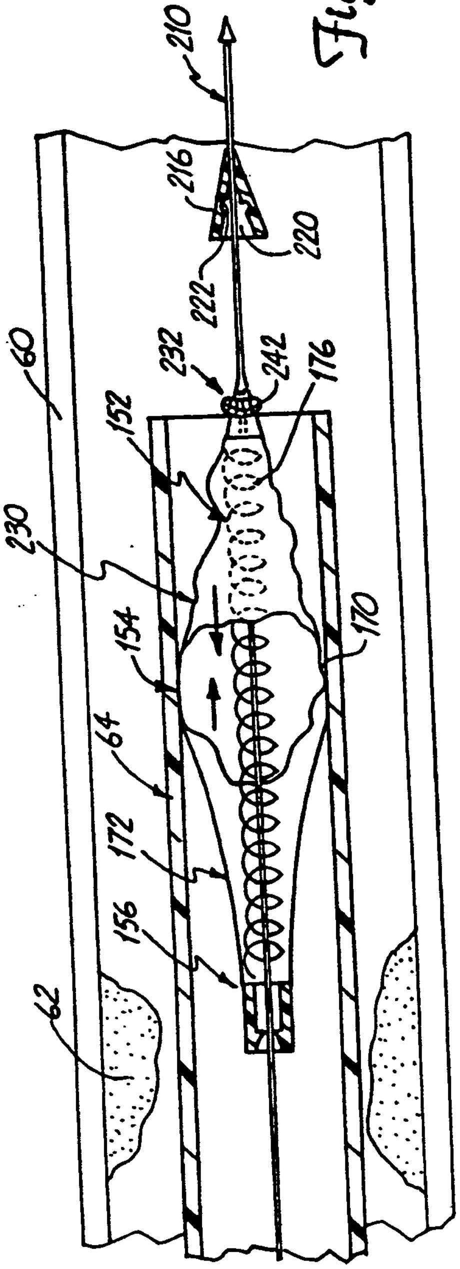

Fig. 18

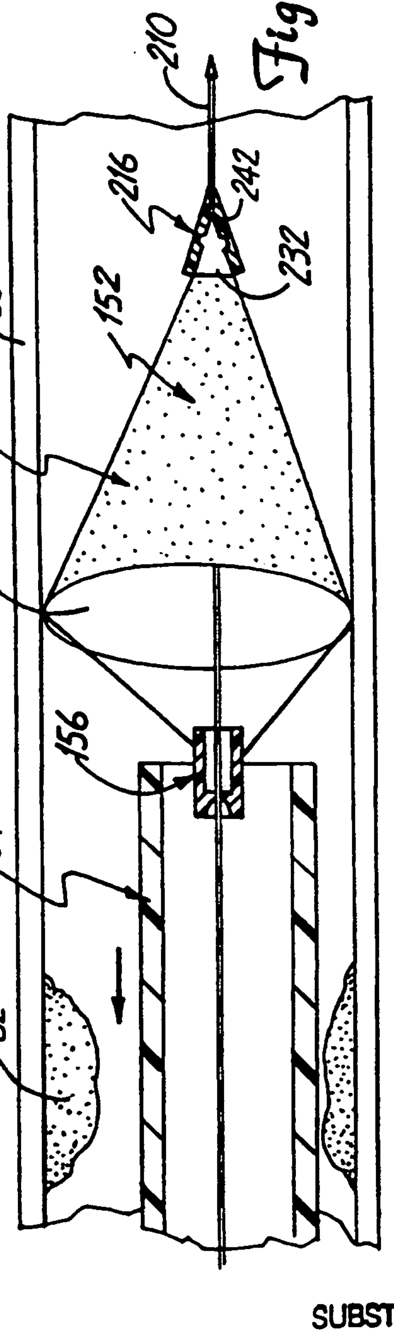

Fig. 19

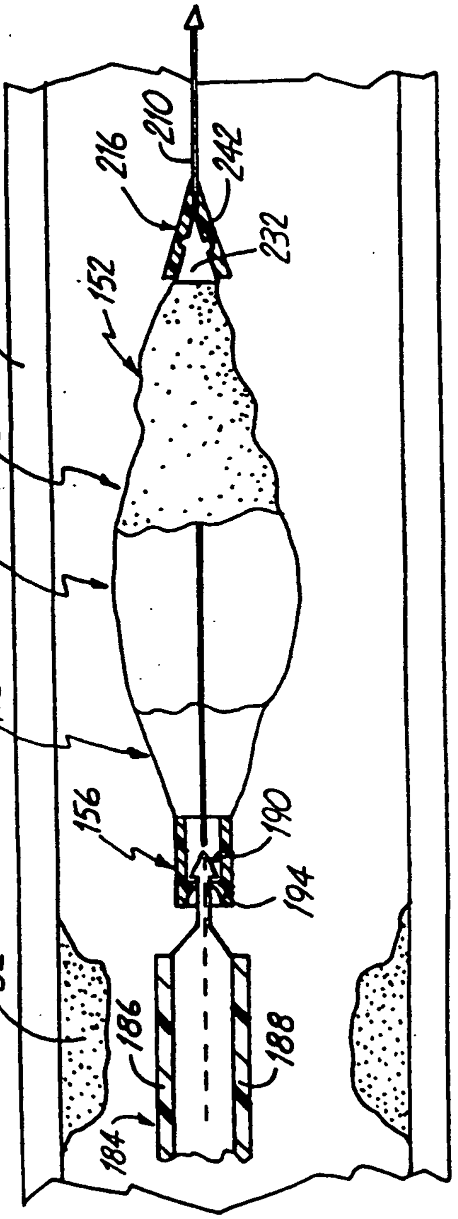

Fig. 20

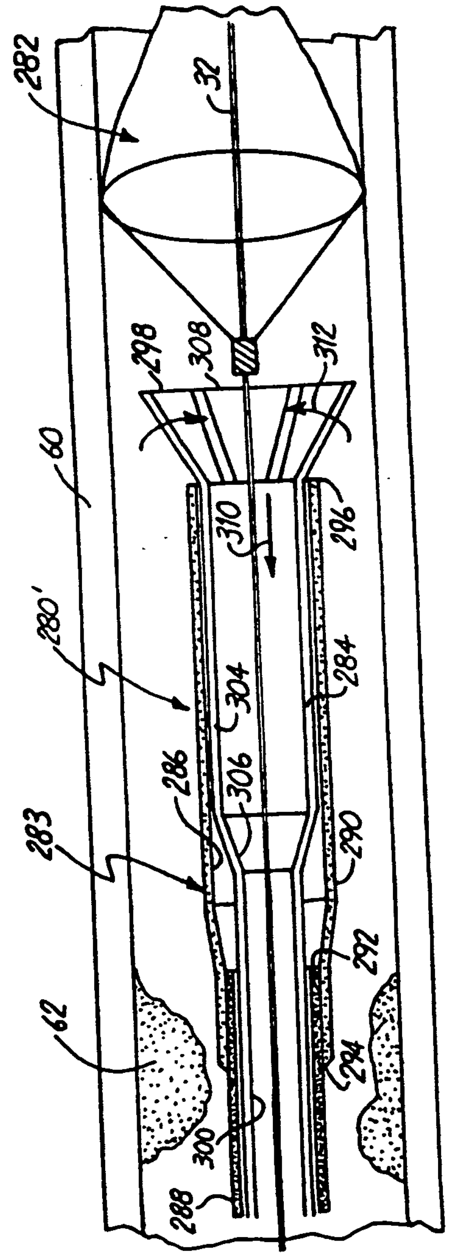

Fig. 21

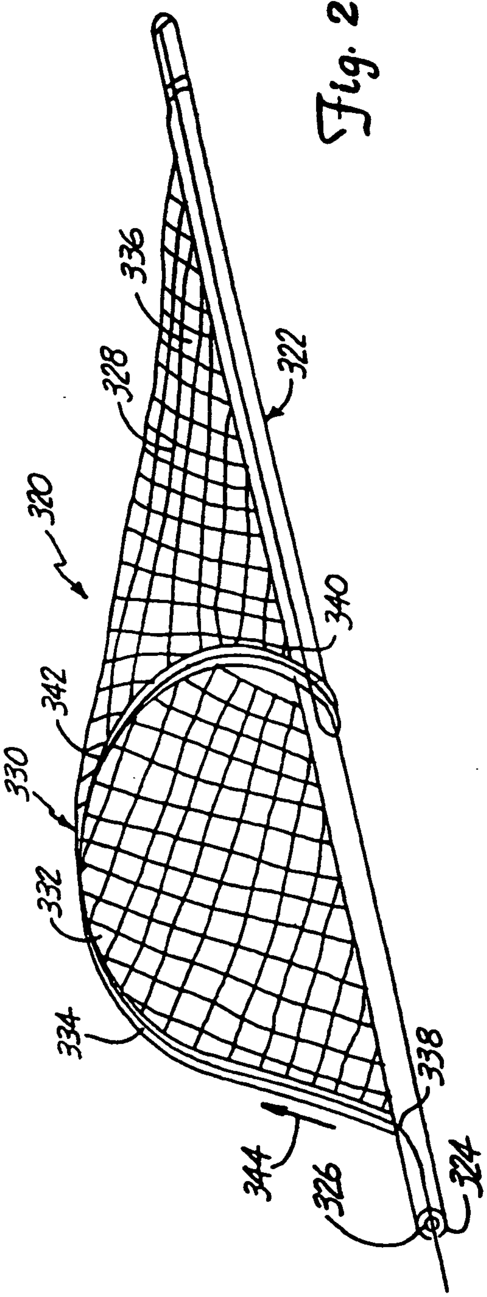

Fig. 22

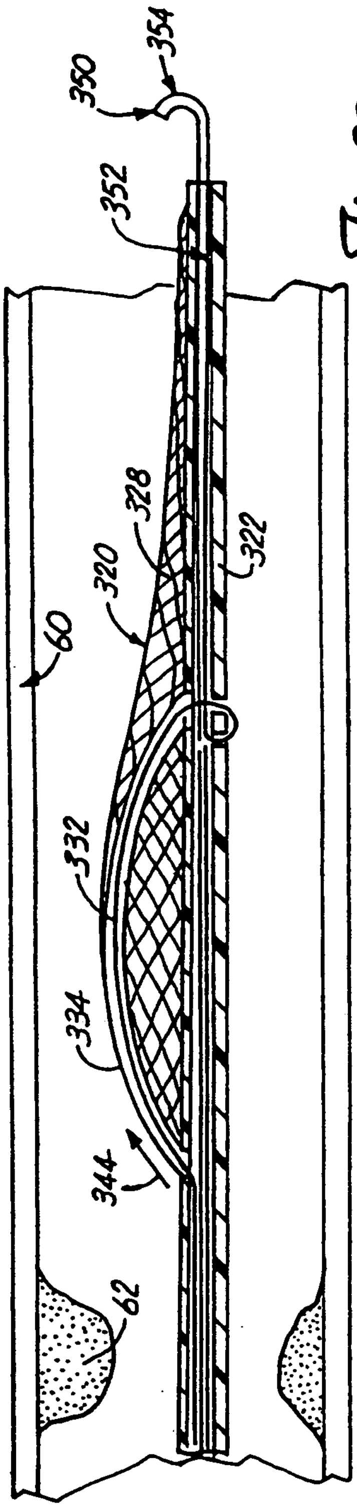

Fig. 23

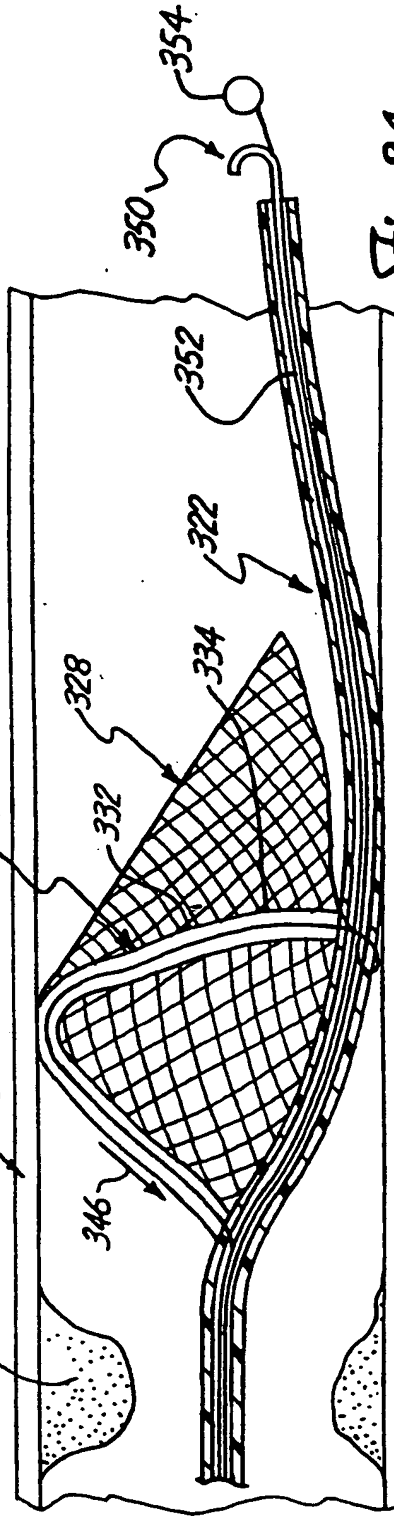

Fig. 24

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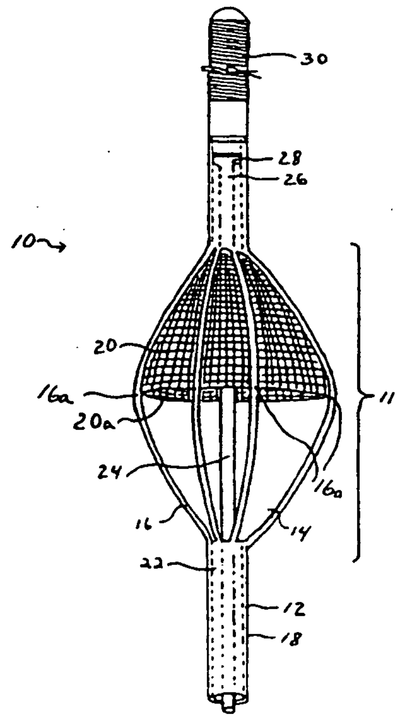
(54) Title: GUIDEWIRE FILTER DEVICE

(57) Abstract

A guidewire filter (10) has an elongate hollow tube (12) with a proximal end, a distal end, an inside, an outside surface, and a lumen formed therethrough. The hollow tube (12) has a plurality of longitudinal slots (14) forming a plurality of longitudinal rib portions (16) near the distal region of the hollow tube (12). An actuating wire (24) with a proximal end, and a distal end is provided. Filter material (20) is positioned within the lumen in the hollow tube (12). An activation handle (38) on the proximal end of the device (10) is provided for pulling the actuating wire (24) relative to the hollow tube (12).



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GUIDEWIRE FILTER DEVICE

Background of the Invention (Field of the invention)

The present invention relates to the field of guidewires, and more particularly to a blood filter guidewire device to be used in percutaneous carotid angioplasty procedures for treatment of carotid artery stenosis and any other hollow conduit disorders

Background of the Invention (Description of the Related Art)

Carotid artery stenosis is a narrowing of the carotid artery due to build-up of atheromatous plaque. Carotid artery stenosis is the most common cause of stroke and stroke is the third leading cause of death and the number one cause of long-term disability in the United States. The standard treatment for patients with carotid artery stenosis is carotid endarterectomy (CEA). CEA is a surgical procedure that involves open exposure and incision of the carotid artery followed by removal of the atheromatous plaque. Currently, physicians perform 120,000 CEA procedures annually in the United States.

A newer procedure called percutaneous transluminal angioplasty (PTA) of the carotid artery has been advocated as an alternative to CEA for the treatment of carotid artery stenosis. The procedure involves insertion of a balloon tipped catheter into the stenotic region of the carotid artery. The physician inflates the balloon against the stenotic arterial wall to dilate the arterial lumen, thereby improving blood flow through the vessel.

PTA may be a viable alternative to and/or possible replacement for CEA. However, preliminary published results of PTA procedures reveal higher stroke/death rates compared to those achieved with CEA. The increased stroke rates result from the dislodgment of intra-arterial embolic material during the angioplasty procedure.

There has been some work done on devices to deal with this situation. For example, U. S. Patent No. 4,723,549 to Wholey et al. describes a catheter designed to slide over a guidewire for dilating occluded or stenotic blood vessels. The Wholey et al. device is a balloon catheter with a collapsible filter portion. The collapsible filter is deployed by inflating a filter balloon positioned near the distal end of the catheter. The catheter also has a dilating balloon set back proximally from the filter balloon for compressing the stenosis. The collapsible filter device comprises a plurality of resilient ribs secured to the catheter at the distal end of the catheter and extending generally longitudinally toward the dilating balloon. Inflation of a filter balloon pushes the ribs outwardly against the vessel wall to stretch filter material secured to the ribs across the vessel to form a cup shaped trap. This filter is supposed to capture fragments of a stenosis loosened by the dilating balloon. Upon deflation of the filter balloon, the resilient ribs retract against the catheter to retain the trapped fragments during withdrawal of the catheter. In the preferred embodiment of the Wholey et al. device, the promixal ends of the ribs projecting generally toward the dilating balloon are moveably secured to a ring that slides along the outside surface of the catheter. In use, the cup-shaped trap filter is extended and then the dilating balloon is inflated. Blood flow established by deflation of the dilating balloon carries stenosis fragments into the filter.

There are several shortcomings with the Wholey et al. catheter. For example, in the first embodiment, nothing positively moves the ribs and the carried filter to the retracted position against the walls of the catheter. Furthermore, the free ends of the ribs could very well entangle with each other, or possibly damage the vessel walls, and/or inadvertently release captured particles from the trap filter. In the second embodiment, a slideable ring moveably retains proximal ends of the ribs. This second ring is slideably positioned on the outside surface of the catheter. In both embodiments, all the filter components are located to the exterior or on the outside of a rather large catheter. During withdrawal of the catheter, there is a possibility that free proximal ends of the ribs (or the slideable ring) can be caught on the vessel walls and thus reopen the trap filter. Moreover, the Wholey et al. catheter, by integrating the trap filter into the design of the catheter gives a physician less flexibility in where the filter is to be positioned relative to the stenosis. Indeed, it would appear that the excessively complex design of Wholey et al would make the device too large to fit and function within the carotid artery.

U.S. Patent No. 5,695,519 to Summers et al. discloses a distal intravascular filter for filtering blood and entrapping and retaining embolic debris. The intravascular filter includes a small diameter hollow guide wire or tube capable of percutaneous placement beyond a carotid stenosis. The distal portion of the tube includes a filter mounted thereon. The filter is deployable from a tightly closed configuration to an open circumference for filtering embolic material from the bloodstream. The filter is deployable between open and closed positions by manipulation of an actuating wire extending from the filter and out the proximal end of the tube. An examination of the design would indicate that at least one major problem with the Summers et al. device is that the actuating wires are too thin. Deployment of the filter mechanism requires pushing the actuating wires along a column of about 175-cm in length. The wires cannot support the force necessary to properly deploy the filter because they cannot be made thick enough to perform their function and constrain to the necessary dimensions of the hollow tube or wire. A second problem is that once the filter is deployed, there is no way to assure that the filter will stay open and be secured against the arterial wall. The system relies on the blood flow to keep it open, which may not be sufficient to maintain an open filter, particularly in a stenotic carotid artery. Thirdly, because of a multitude of moving parts, the system would likely be expensive to produce and difficult to assemble, and would likely encountering similar problems of as that of the Wholey et al catheter, including inability to fit all the parts into a tight space.

There accordingly remains a need for a guidewire filter device that can be used in lieu of conventional guidewires during percutaneous carotid angioplasty procedures to capture any dislodged intra-arterial embolic material.

Summary of the Invention

One object of the invention is to provide a guidewire filter device that is compatible with current carotid angioplasty balloon catheter systems, viz., can be used in place of conventional guidewires.

Another object of the invention is to provide a guidewire filter device in which filter or mesh material is located inside of the guidewire filter rather than outside the guidewire or catheter shaft to provide a relatively smooth exterior surface. This enables smoother passage of the device within the artery and may decrease the risk of possible fragmentation and subsequent emboli of plaque particles of the stenotic lesion and/or damage to the arterial wall.

Yet another object of the invention is to provide a guidewire filter device including a ribbed cage/basket design that expands to seat against the arterial wall, forming a self-supporting and non-collapsing seal for the filter mesh against the arterial wall. Blood and particles will accordingly be required to travel through the filter mesh rather than around it. While the blood and its components will be able to freely travel through the filter mesh, those particles that are larger than the pore size of the filter mesh, e.g. intra-arterial embolic material, will be prevented from traveling further and will be effectively captured.

A further object of the invention is to provide a guidewire filter device in which the filter is deployed by pulling (rather than by pushing) on an actuating wire allowing use of a thinner wire.

A final object of the invention is to provide a guidewire filter device that is simple in design, involves relatively few parts, is economical to manufacture, and that is reliable and safe in its operation.

These and other aspects of the present invention are afforded by providing a guidewire filter device that comprises a distal filter element contained within a hollow tube/wire housing. The outer diameter of the device will preferably not exceed 0.13 cm (0.050 inches) and even more preferably will not exceed 0.0889 cm (0.035 inches) so as to be compatible with current carotid angioplasty balloon catheter systems. For other uses involving larger hollow conduit disorders, a larger size can be utilized. The length of the guidewire will preferably be approximately 150 to 190 cm to allow for catheter exchange during the PTA procedure, but can be of different lengths as required. The filter element or portion is located at the distal end of the device. There are longitudinal slots or "ribs" located circumferentially around the filter housing. The slots are ideally oriented longitudinally, but can be oriented spirally or in other orientations. Filter mesh material is located inside the filter element and is attached to the inner distal section of the ribs. Alternately, the filter material can be affixed to outer surfaces of the ribs, or can even be sandwiched between the outer ribs and outer rib overlay portions to help secure the filter material in place. In yet a further embodiment, the ribs themselves can be sandwiched by a section of an inner filter material and a section of outer filter material, with the inner and out filter materials being affixed to inner and outer surfaces, respectively, of the ribs. These inner and outer filters can also optionally affixed at least partly together. In this double filter material embodiment, the inner and outer filter materials could be made of thinner filter material so that the inner filter material can be made to better fit into the interior surface of the guidewire. An actuating wire attaches to the distal most end of the filter housing and passes through the entire length of the guidewire and out the proximal end. A handle/remote activation device attached to the proximal end attaches to and operates the actuating guidewire.

During a PTA procedure, a physician will use fluoroscopy to steer the guidewire filter device of the invention into place in the carotid artery distal to the stenotic lesion. The physician will then place the balloon angioplasty catheter over the guidewire filter device of the invention. The physician will then use a handle/remote activation device at the proximal end of the device to deploy the filter element or portion at the distal end of the device. The ribs of the filter element will expand into a cage/basket formation. As the cage opens, the folded filter mesh material will open along with the ribs, forming an inverted cup-shaped trap for any embolic material broken loose during the balloon angioplasty procedure. The ribs push against the inner arterial wall, forming a tight seal with the inner arterial wall and the expanded filter mesh covers the opening of the artery. The physician then performs the PTA procedure. After the procedure, the physician will collapse the filter assembly either by withdrawing the guidewire filter housing into the distal balloon catheter tip, and/or by using the handle/remote activation device to release tension on the actuating wire to allow the ribs to reflex back down. Any embolic material resting against the inside of the filter mesh will thus be captured. When the filter element is retracted and closed, any embolic material will be withdrawn from the arteries along with the guidewire filter device of the invention.

The new design of the invention thus has a unique features that render it significantly different and markedly better than other devices used to perform similar functions. The innovations and improvements intrinsic to the current guidewire filter design include the following:

1. The design allows for an accurate and reliable means to activate and deactivate the guidewire filter device.

2. The filter material is preferably stored and operated inside the guidewire filter rather than outside the guidewire or catheter shaft. This allows for maintenance of a smooth exterior, enabling easier movement of the device within the artery and decreases the risk of possible damage to the arterial wall.

3. The ribbed cage/basket design expands to seat on the inner arterial wall, forming a self-supporting and non-collapsing seal for the filter against the inner arterial wall. Accordingly, blood and loose particles will be forced to travel through the filter mesh rather than around it. Those particles that are larger than the filter mesh will be captured and prevented from traveling further by the filter mesh.

4. The filter deploys by pulling the actuating wire rather than pushing on it, allowing use of a narrow gauge wire that is compatible with the inner lumen of the guidewire.

5. The design is simple, reliable, involves relatively few parts, and enables an efficient and low cost process to be used to manufacture the device.

Brief Description of the Drawings

The appended drawings demonstrate the above features, advantages and objects of the present invention.

Figure 1 is a partial perspective view of a first embodiment the invention showing the guidewire filter portion of the device in the open position.

Figure 2a is a partial side view of the invention of Figure 1 showing the guidewire filter portion in the closed position with radipaque markers.

Figure 2b is a partial side view of the invention of Figure 1 showing the guidewire filter portion in the closed position with radipaque rib portions.

Figure 3 is a cross-sectional view through view lines 3-3 of Figure 2.

Figure 4 is a partial side view of the proximal end of the guidewire filter device showing the guidewire remote activation handle.

Figure 5 is a partial side view showing a portion of a second embodiment of the invention wherein the guidewire filter portion of the device has spirally formed slots and rib portions.

Figure 6 is a cross-sectional view of a third embodiment of a guide filter device in a closed position wherein the filter material is affixed to the outside surface of the rib portions.

Figure 7 is a cross-sectional view of a third embodiment of a guide filter device in a closed position wherein the filter material is sandwiched between an outside surface of the rib portions and rib cover portions to secure the filter material in place on the rib portions.

Figure 8 is a cross-sectional view of a forth embodiment of a guide filter device in a closed position that includes an inner and an outer section of filter material, wherein the rib portions are sandwiched between inner and outer sections of filter material.

Figure 9 is a partial perspective view of a first embodiment the invention protruding from the distal end of a guide tube or catheter with which the device is adapted to be utilized and with the guidewire partially retracted into the guide tube or catheter to assist in returning the rib portions and the filter material (filter basket) to the closed position.

Detailed Description of the Preferred Embodiments

Referring to Figure 1, the guidewire filter 10 on the invention is shown in its open position, forming a filter basket 11. Guidewire filter 10 consists of an outer hollow tube 12 with a plurality of elongate slots 14 formed circumferentially around and in a longitudinal orientation to define rib portions 16 (see also Figure 2a). Outer hollow tube 12 is composed of a shape memory alloy, or other metal or composite material (or any other known materials) that has the appropriate strength and shape characteristics to conform to the filter basket requirements. Outer hollow tube 12 protects the guidewire filter 10 while the filter 10 is manipulated into position in the arteries. Because the outer hollow tube 12 is smooth on its exterior surface 18, it enhances the maneuverability of the guidewire filter 10 as it is being manipulated through arteries, and when positioned as required. Figure 2a shows slots 14 formed in a longitudinal orientation to form longitudinal rib portions 16. Optionally, radiopaque markers 19a and 19b can be positioned on the device adjacent to distal and proximal ends, respectively, of the slots 14 and 16. By measuring the spacing of these radiopaque markers 19a and 19b during a procedure, the physician can determine (e.g. by fluoroscopy) to what extent the filter basket 11 is expanded or contracted. Additional radiopaque markers 19c can also be formed near the center points of the rib portions 16 so that the physician can determine the greatest point of expansion of the filter basket 11 against the inside wall of the vessels when expanded (not shown.) In lieu of specific radiopaque markers, all or portions of the rib portions 16 themselves can be painted, plated, and/or imbued with radiopaque material (e.g. gold, platinum, etc.) as best shown in Figure 2b.

Referring to Figures 1 and 3, filter material 20 is attached to the inside of at least some of and preferably all of ribs 16 and filter material 20 expands out with filter basket 11 when the mechanism is deployed. In the closed condition as shown in Figures 2 and 3, filter material 20 is stored in the space 22 between outer tube 12 and the inner actuating core wire 24. The space 22 is a lumen in the hollow tube 12.

As shown in Figure 1, the filter material 20 is affixed to about the distal most one half of the rib portions 16 in the form of an inverted cup-shaped net when expanded. Indeed, the edge 20a of the filter material 20 can preferably be in line with the most expanded region or points 16a of the rib portions so that when the filter basket 11 is expanded in an artery, a good seal will be formed against the arterial wall so that any fragments that might have broken free and are floating in the blood are captured by the filter basket 11. As shown in Figure 3, the filter material 20 is affixed to the inside walls 32 of ribs 16, e.g. by adhesives 34 or other means. Filter material 20 is shown as being folded to remain within space 22 between the inner surface 32 of hollow tube 12 and actuating wire 24. However, as noted above, by use of flexible, stretchable, elastic, and resilient filter material, folding of the filter material can be reduced or eliminated. While an arrangement with eight rib portions 16 is shown, the device 10 can be made with a greater or lesser number of rib portions 16.

The filter material 20 is selected to pass vital elements in the blood stream (such as red blood cells, white blood cells and platelets) while trapping dislodged embolic material from the carotid angioplasty procedure. The filter 10 configuration will be designed to minimize interruption of blood flow to the brain. In the preferred embodiment, the filter material 20 is composed of an elastic mesh material that expands and contracts with the cage/basket 11. In an alternate embodiment, the filter material 20 is composed of a non-elastic mesh material that is folded inside the filter housing and unfolds as the basket 11 opens (as is best shown in Figure 3.) Another option is to design a drop in filter cartridge to reduce the complexity of the filter design and manufacturing costs (not shown.)

As shown in Figures 1 and 3, the actuating wire 24 is shown passing through passageway 22 inside the outer hollow tube 12. The actuating wire 24 provides the leverage point for activating the filter basket 11. The actuating wire 24 comprises stainless steel or other metal or composite materials with the appropriate strength and shape characteristics to conform to the actuating wire specifications. The actuating wire 24 is permanently attached (e.g. by adhesives or otherwise) at its distal end 26 to a position 28 inside outer tube 12 that is distal to the rib portions 16. By pulling on the actuating wire 24 (and/or pushing on the outer hollow tube 12), the distal end of outer hollow tube 12 will cause rib portions 16 and the carried filter material 20 to expand outward, forming the cage or basket shaped filter 11 as shown in Figure 1. To provide as much room as possible for the filter material 20 to fit inside the outer hollow tube 12, the actuating wire 14 preferably should be only thick enough to carry the force required to activate the filter assembly 10.

Referring to Figures 1 and 2a, distal to the filter housing 11 is a flexible atraumatic guidewire tip 30 consistent with current guidewire technology.

Referring to Figure 4, the proximal end 36 of the guidewire filter 10 is shown with a guidewire remote activation handle 38. The activation handle 38 may be removed so that the angioplasty balloon catheter may be placed over the guidewire filter 10 and positioned in the carotid artery. When attached, the activation handle 38 provides a means for pulling of the actuating wire 24 relative to the hollow tube 12 so that the filter basket 11 can be opened (and also closed) in an incremental fashion. The motion can be conveniently controlled by a ratcheting/locking mechanism 40 so that the physician has total control when opening and closing the filter basket 11. As noted above, radiopaque markers 19a, 19b, and 19c can be positioned on or adjacent to the ribs portions to help the physician determine the relative state of expansion or contraction of the filter basket. Since the ratcheting/locking mechanism 40 is for pulling and pushing on the activation wire 24, its position relative to the casing 41can also provide the physician with information. Increment or calibration markers 43 can be formed on the casing 41 for this purpose as well. Since there may be cases wherein the physician would not want to completely collapse the filter basket 11 (e.g. if it is too full of collected embolic particles does not want to compress them too much), the ability to fairly well know the degree of expansion or contraction can be important.

In a second embodiment of the device 50, a portion of which is shown in Figure 5, slots 52 are formed in a spiral orientation to create spirally oriented rib portions 54. As with the first embodiment of Figures 1-3, filter material (not shown) is attached to the inside of the rib portion.

Turning to Figure 6, a cross-sectional view of a third embodiment of a guide filter device 60 is shown in a closed position. In this embodiment, the filter material 62 is affixed (e.g. with adhesives, welding, sutures, mechanically, or by other known means) to an outside surface 64 of the rib portions 66. As in the first embodiment, the rib portions 66 are separated by slots 68. The filter material 62 can preferably comprise stretchable and resilient material to reduce or eliminate the need for folding of the filter material 62 into the space 70 between the inside surfaces 72 of the rib portions 66, and the actuating wire 74.

Figure 7 is a cross-sectional view of a third embodiment of a guide filter device 80 in a closed position wherein the filter material 82 is sandwiched between an outside surface 84 of the rib portions 86 and a rib cover portions 88 affixed to the outside of the rib portions 86. The rib cover portions 88 can be secured with adhesives, welding, sutures, mechanical means (such as a snap fitting rib cover portions 88) to secure the filter material in place.

Figure 8 is a cross-sectional view of a forth embodiment of a guide filter device 90 in a closed position that includes an inner section of filter material 92 and an outer section of filter material 94. The inner section of filter material 92 is affixed to inner surfaces 96 of rib portions 98 (e.g. with adhesives, by welding, or other known means), and the outer section of filter material 94 is likewise affixed to outer surfaces 100 of rib portions 98 to thereby sandwich the rib portions 98 between the inner and outer sections of filter material 92 and 94. Use of two sections of filter material 92 and 94 permits thinner filter material to be used and disposed within the lumen 102 of the guidewire 90. As before, an actuating wire 104 is disposed in the lumen 102. The outer section of filter material 94 (as well as inner section of filter material 92) are preferably constructed of flexible, stretchable, elastic, and resilient material so that after tension is released on the actuating wire 104 in the lumen 112, the sections filter material 92 and 94 will provide extra force to help return the expanded rib portions 98 back to a the undeployed state shown in Figure 8.

Referring to Figure 9, a partial perspective view is shown of the first embodiment the guidewire of the invention 10 and a guide tube 110. The guidewire 10 is shown protruding from the distal end 112 of the guide tube or catheter 110. Moving the guide tube (or a catheter) 110 distally forward and/or retracting the guidewire 10 into the guide tube or catheter 110 will cause the distal end 112 of the guide tube 110 to impinge on the proximal most confines of the rib portions 16 and will assist in returning the rib portions 16 and the filter material (filter basket 11) to the closed position and thereby either partially or completely closing up of the filter basket 11. The distal end 112 of the guide tube or catheter 110 can optionally have a radiopaque marker 114, and when used in combination with optional radiopaque markers 19a, 19b, and/or 19c as shown in Figure 2a (or radiopaque marked rib portions as shown in Figure 2b) can be used to determine the relative position of the distal end 90 of the guide tube or catheter 92 to the filter basket 11.

While the device 10 has been discussed with particularly reference to its use in performing percutaneous carotid angioplasty procedures, it could be used in other applications where capture of embolic material is desirable. Also, at least in the area of the rib portions of the various embodiment of the device, the material will preferentially return to a straight and unexpanded shape when tension on the actuating wire is released.

The drawings and the foregoing description are not intended to represent the only form of the invention in regard to the details of this construction and manner of operation. In fact, it will be evident to one skilled in the art that modifications and variations may be made without departing from the spirit and scope of the invention. Although specific terms have been employed, they are intended in a generic and descriptive sense only and not for the purpose of limitation.

WE CLAIM:

1. A guidewire filter device, comprising:

an elongate hollow tube with a proximal end and a distal end, the hollow tube having an inside surface and an outside and defining a lumen formed therethrough, the hollow tube having a plurality of slots formed near the distal end, the plurality of slots defining a plurality of rib portions;

an actuating wire with a proximal end and a distal end, the actuating wire distal end of the actuating wire being affixed to a point inside of the hollow tube that is distal to the rib portions; and

filter material positioned within the lumen in the hollow tube with the filter material being affixed to portions of rib portions; whereby by pulling the proximal end of the actuating wire relative to the hollow tube, the rib portions will expand outwardly and open up the filter material in the form of a filter basket.

2. The guidewire filter device of claim 1, wherein the slots and rib portions are formed longitudinally in the hollow tube.

3. The guidewire filter device of claim 1, wherein the filter material is folded and is positioned in the lumen and is attached to the inside surfaces of the rib portions.

4. The guidewire filter device of claim 1, further comprising an activation handle on the proximal ends of the hollow tube and the actuating wire, the activation handle comprising a means for pulling of the actuating wire relative to the hollow tube so that the filter basket can be opened in an incremental fashion.

5. The guidewire filter device of claim 4, wherein the activation handle is detachably attachable to the proximal ends of the hollow tube and the actuating wire.

6. The guidewire filter device of claim 1, wherein the filter material is sized and positioned such that it is affixed to the inside surfaces of about the distal most half of the rib portions.

7. The guidewire filter device of claim 1, wherein the filter material is affixed to the inside of the rib portions with adhesive.

8. The guidewire filter device of claim 1, wherein the filter material comprises stretchable and resilient material.

9. The guidewire filter device of claim 1, further comprising a flexible atraumatic guidewire tip.

10. The guidewire filter device of claim 1, wherein the slots and rib portions are formed in a spiral orientation in the hollow tube.

11. The guidewire filter device of claim 1, wherein the elongate hollow tube has an outer diameter that is 0.13 cm or smaller.

12. The guidewire filter device of claim 1, wherein the filter material is affixed to an outside surface of the rib portions.

13. The guidewire filter device of claim 12, further comprising rib cover portions that overlay the filter material on the rib portions.

14. The guidewire filter device of claim 7, further comprising an outer section of filter material that is affixed to outside surfaces of the rib portion.

15. The guidewire filter device of claim 1, further comprising radiopaque markers formed adjacent to proximal and distal ends of the rib portions.

16. The guidewire filter device of claim 1, further comprising radiopaque markers formed about midway on the rib portions.

17. The guidewire filter device of claim 1, further comprising radiopaque material applied into or onto at least portions of the rib portions.

18. The guidewire filter device of claim 1, further comprising a guide tube through which the guidewire filter device is slideably positionable.

19. The guidewire filter device of claim 1, wherein at least in the area of the rib portions, the elongate hollow tube material comprises memory material which will tend to cause the rib portions to preferentially return to a straight and unexpanded shape.

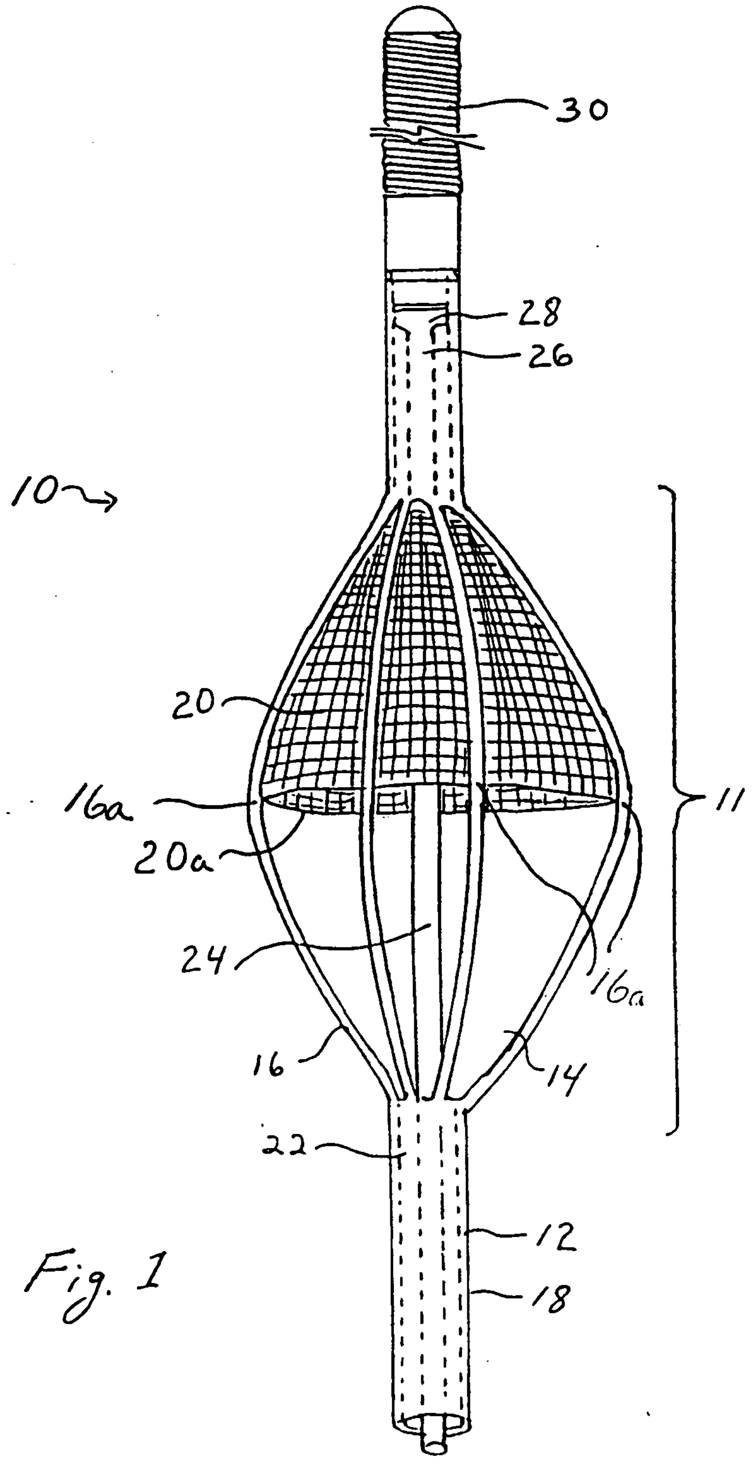


Fig. 1

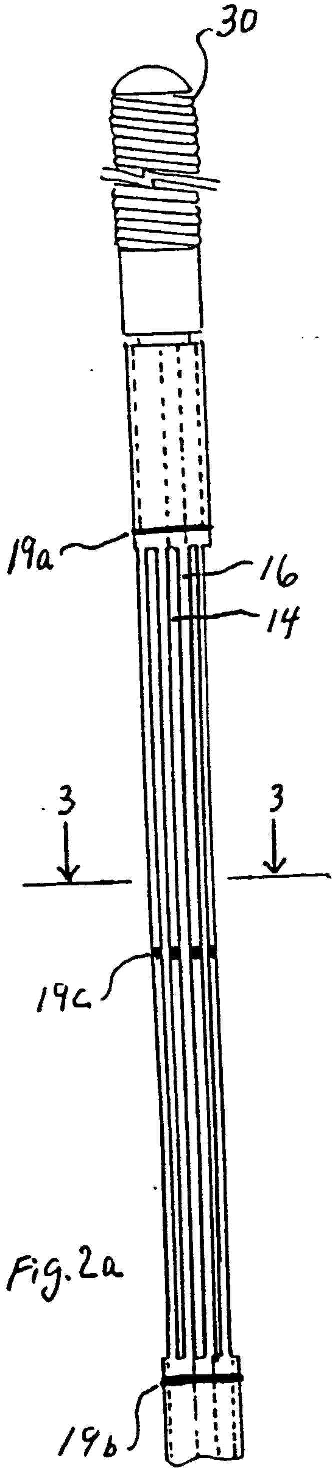


Fig.2a

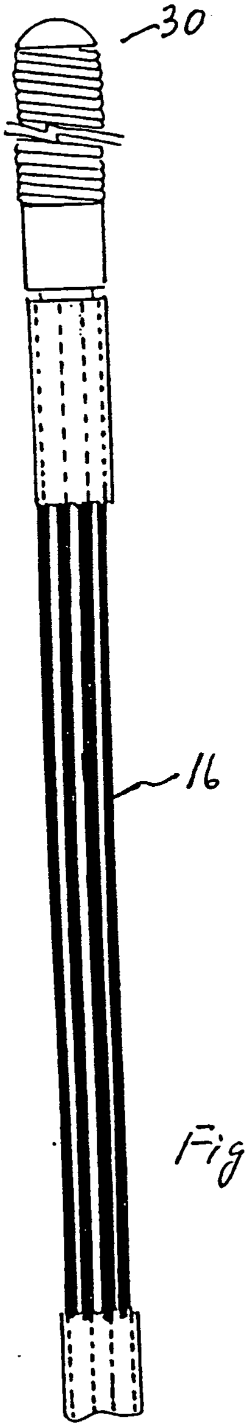


Fig.2b

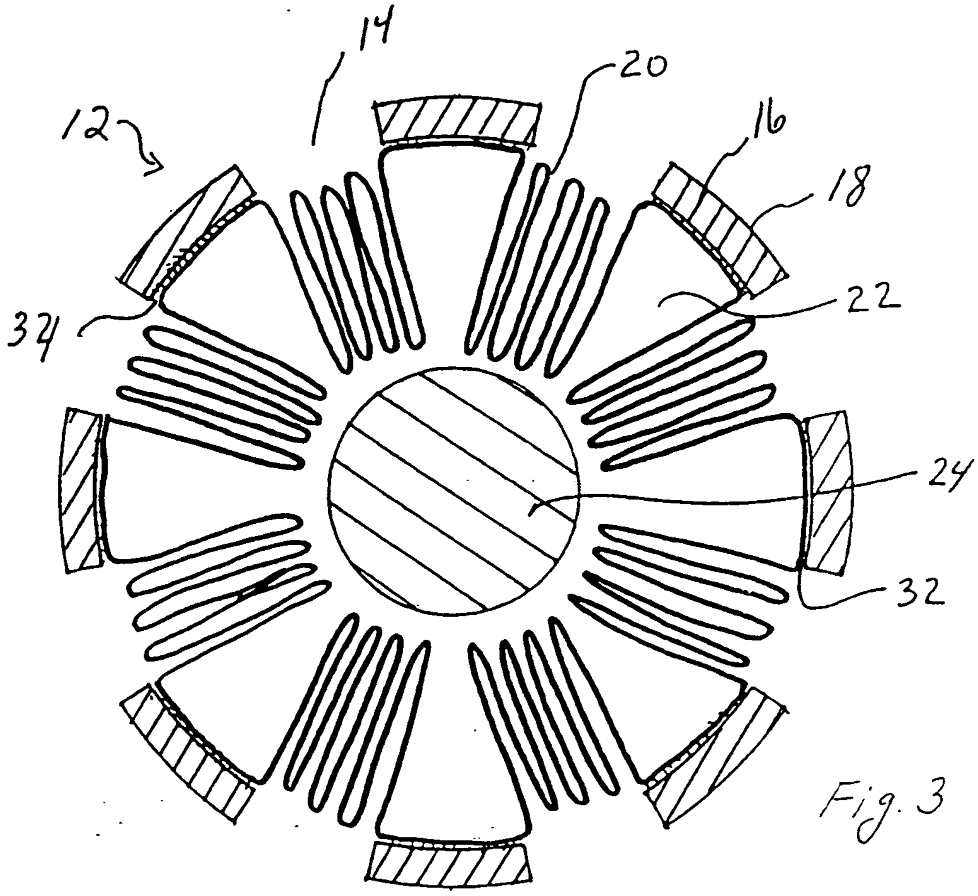
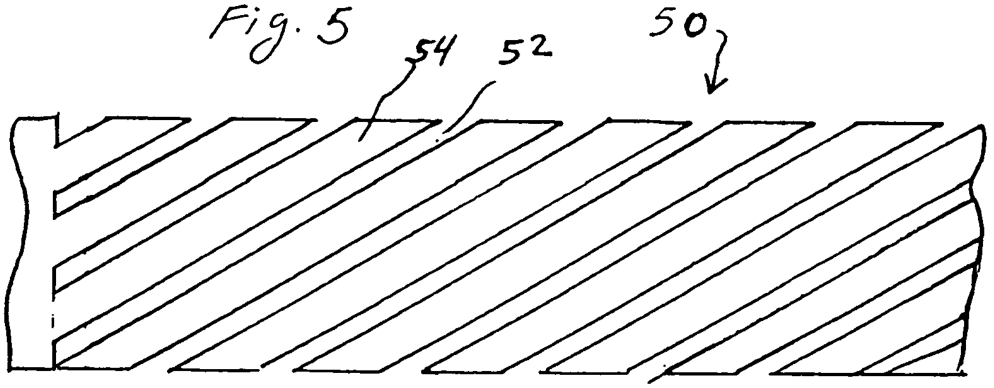


Fig. 3

Fig. 5



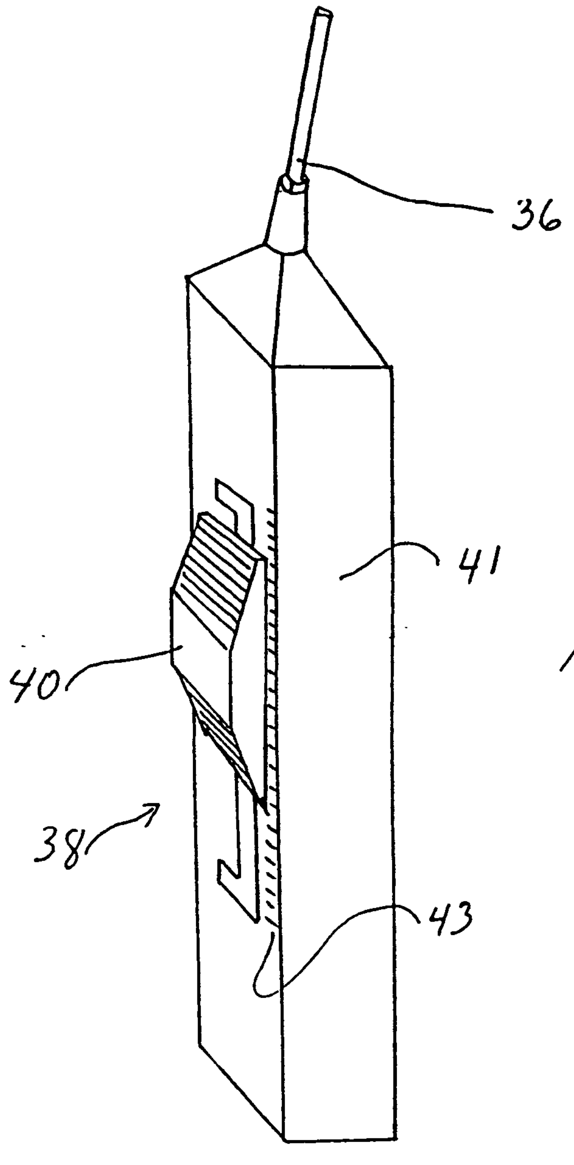


Fig. 4

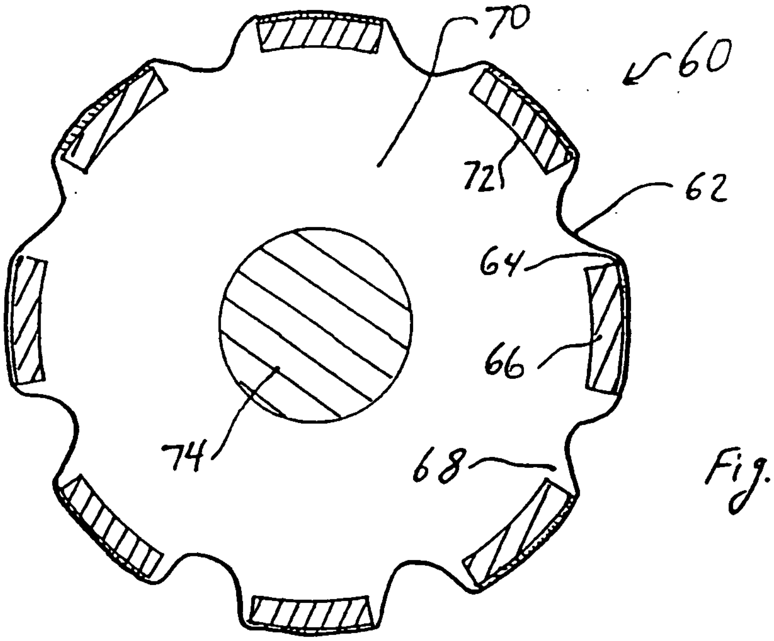


Fig. 6

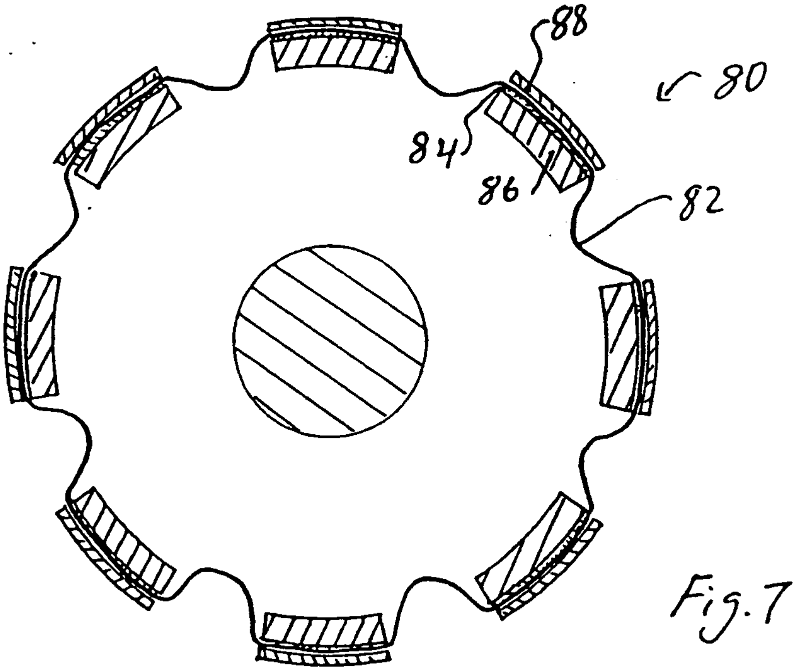


Fig. 7

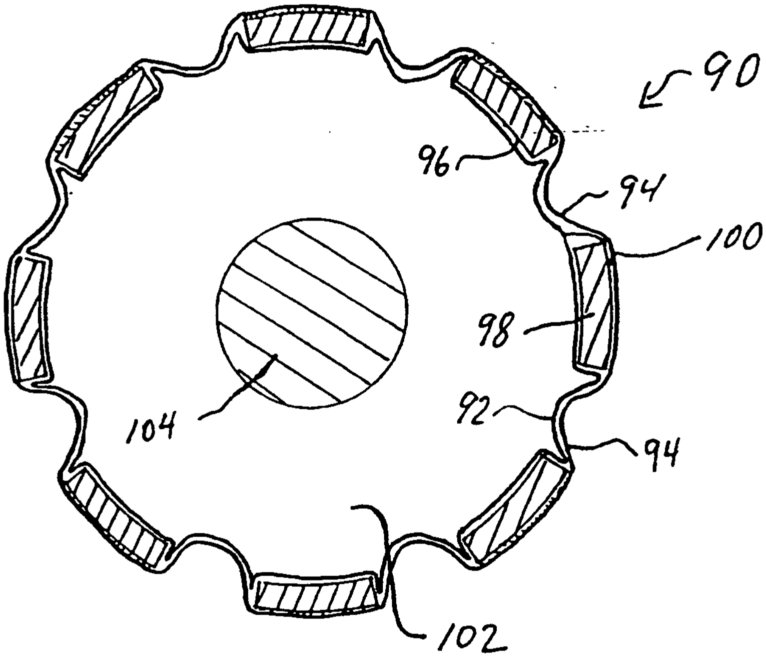


Fig. 8

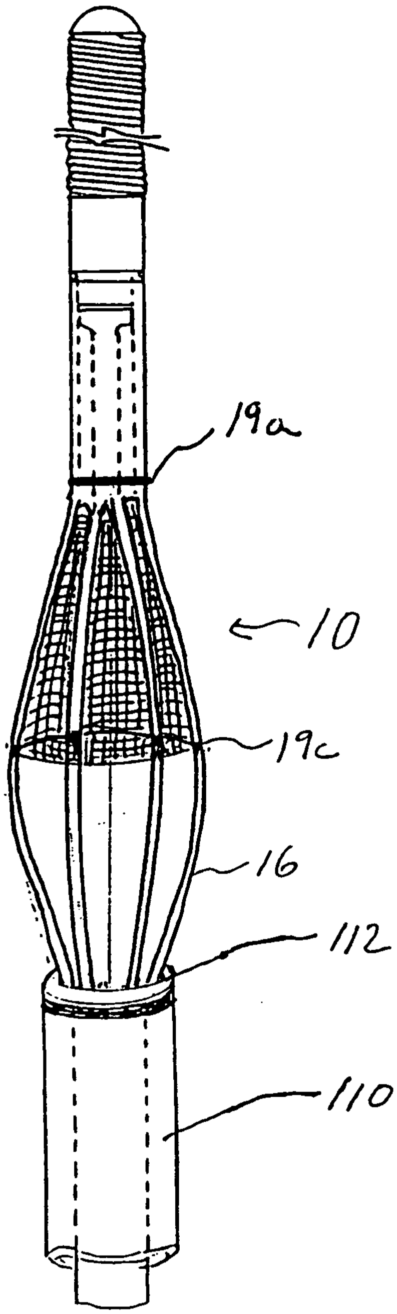


Fig. 9

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US99/05163

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) :A61B 17/00
US CL :604/104; 606/200
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/104; 606/200

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 5,053,008 A (BAJAJ) 01 October 1991, entire document.	1-19

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier document published on or after the international filing date
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"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
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Date of the actual completion of the international search
23 APRIL 1999

Date of mailing of the international search report
06 MAY 1999

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